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CENTER FOR DEVICES AND RADIOLOGICAL HEALTH

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CDRH GUIDANCE DEVELOPMENT AND PRIORITIZATION WORKSHOP

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FDA White Oak Campus
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GUIDANCE DEVELOPMENT BEST PRACTICES PANEL DISCUSSION and
CDRH GUIDANCE PRIORITIES PANEL DISCUSSION

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M E E T I N G

(9:01 a.m.)

MS. STADE: Well, good morning everyone, and welcome, everyone here in the White Oak Campus and those of you also participating by webcast. I'm Nancy Stade, the Deputy Director for Policy, Center for Devices and Radiological Health, and I'm very pleased to welcome you all to the CDRH Guidance Development and Prioritization Workshop.

That's my first slide. I hope you like it.

(Laughter.)

MS. STADE: I'm going to explain the relationship to the guidance program a little bit later, but let me just start with a few housekeeping bits of information.

First of all, the restrooms are located across the registration lobby and down the hallway behind the snack kiosk. There's a concession kiosk in the registration lobby where you can purchase food and beverage items during breaks and at lunchtime.

Guest wifi access is available in the Great Room area. For the access code, it should be posted at the registration desk. And we do ask that you mute your phones and computers while you're in the auditorium and answer any phone calls in the lobby. The phone numbers for taxis are available in the registration lobby as well.

Okay. So, you have an agenda. You can see the format for this

meeting will be to have a series of presentations in the morning. And these will reflect different expertise and perspective on guidance development and best practices. After those presentations, there will be an opportunity for questions and answers from the audience, in addition from our web audience, and after that we're going to have lunch.

The afternoon will feature a panel on GGP Best Practices with several folks from within FDA and also from our external stakeholders. And we'll then have a presentation on CDRH's process for prioritization of guidance documents, followed by a second panel on the subject of guidance prioritization. Each of the panel sessions will be moderated, and following both there will be another opportunity for question and answer from the audience, from both of our audiences.

We do encourage you to submit comments or ask questions. We will permit members of the audience to pose questions or to make comments by writing them on index cards we'll collect from the registration desk, or by stepping up to a microphone.

For those of you participating by webcast, submit questions or comments to cdrhworkshopcomments@fda.hhs.gov.

Links to the meeting transcript and the archived webcast will be posted at the workshop's registration webpage approximately six to eight weeks after the meeting.

All participants are encouraged to submit comments after the

meeting to the docket, following the instructions in the *Federal Register* Notice. The comment period closes on July 7th.

Each panelist and commenter should identify themselves before speaking. All righty. There's housekeeping.

So, if you're here, I assume it's because you have an interest in guidance. And whether that's an interest just in FDA's guidance program, the CDRH guidance program particularly, or really just in good government practice, I assume that's why you're here, and I really do think that's great that folks are so interested in this program.

I admit, I find it a little surprising at times just the level of interest. And if you're from our external stakeholders, I'm sure this is a topic you discuss amongst yourselves. I know you discuss it with us. I know at times you discuss it with our elected representatives. It is the topic of conversation in many different forums.

I know you're aware, those of you on the outside, the level of interest within your organizations at how guidance is developed and in what we say in our guidance documents. What you may not know is the level of interest within FDA and CDRH in guidance documents as well, even among folks who aren't very involved in the guidance program day to day.

Something I find very interesting because in my own experience, my own professional life, I may be in a meeting on the 510(k) program, combination products, on some legislative development, or as

something as mundane as stents. And it always at some point comes around that the problem we thought we were talking about it's not a problem with stents with 510(k). It's a problem with the guidance program. It's a very interesting phenomenon. And some people like to refer to that as the guidance process, and I'll talk to that a little bit more later.

What I'm getting at here is the guidance program is, and I suppose always will be, just a little bit controversial. I suppose it's because we use the program to do something that's very important. This is how we share our policy, our intention for how we are going to implement our regulatory authorities with our stakeholders and with individuals who will be profoundly affected by how we implement our authorities.

So, it really probably shouldn't be surprising that as long as I've been engaged in guidance and the guidance program, it's had its admirers and it's had its detractors. If you work closely in guidance, as I do, you may at times feel a little bit like the hand servant to an incredibly demanding yet magnetic personality, someone who makes outrageous demands of you, who alienates those who should be supporters, and every now and then throws a cell phone at your head or, more likely, a very heated congressional inquiry.

And I hope that explains my first slide. So, what I'm trying to say basically is the guidance program is just a little bit of a diva. It's something attractive and compelling, yet demanding, and at times polarizing.

So, with that, let me just go through a few of the basics on

guidance. And, again, I assume if you're here, it's because you're very interested in the guidance program. At the same time, I'd like just give the fundamentals. I hope you won't be insulted. You're probably most of you very aware of most of this. At the same time, I do think the conversation will be improved by everybody starting with the same baseline of knowledge.

So, this slide is really just the basics of GGP history. Before we had GGP provisions in law and regulation, we had guidance on guidance. And that was pre-'97. We actually had a GGP guidance document that has many of the principles that ultimately made their way into the law, actually in 1997 with the FDA Modernization Act, 701(h). And that provision sets out the fundamentals of guidance: what's important about a guidance program; what does having guidelines for developing guidance do for us.

Well, the idea of public participation, critical; the non-binding nature; and then also this idea that you could have a Level 1 and a Level 2 guidance documents. We don't do a lot of Level 2 guidance documents, but there might be instances -- for example, we're doing a minor change in policy, a minor update, a technical update to a guidance that exists. Level 2 might be appropriate.

And then the last piece of law, if you will, that governs guidance is a regulation, 21 C.F.R. 10.115. It captures a lot of what's in 701(h) and a little bit more. And that's really the government structure for our guidance program.

So, what is guidance? Again, this comes from 10.115. And I think if you look at the first bullet, what's really important is the final clause: the idea that guidance is the Agency's interpretation of our policy on a regulatory issue. So, we can give recommendations to folks like consumers, healthcare practitioners, individuals that we don't regulate in the form of a safety communication or some other communication. When we're telling our regulated entities that this is how we're going to implement our authorities, then we'd better do it by guidance. That's the basic principle. And I think that's an important nugget to keep in mind when you think of what is guidance, what isn't guidance.

The point of the second bullet really is that it's not the form that matters. So, guidance can be all these things, all these different kinds of documents that relate to all these different issues. The point of that is, let's say instead of providing a presentation on GGPs, I decided I was going to get up here and I was going to tell you how to submit a 510(k) on infusion pumps. Well, just because it's in a PowerPoint presentation doesn't mean it's not guidance. That needs to go through our GGPs. I think that's the point of the second bullet. It's really the concept that matters, not the form. When you're providing interpretations of regulatory policy, that's probably something where you should be thinking of following the GGPs.

What isn't guidance documents? Well, there are some things that aren't guidance documents. We can make internal SOPs and procedures.

We can do agency reports. As you know, if you've followed FDASIA, there are several report requirements. There's a requirement that we do a report on 510(k) modifications. There was a requirement that we do a report on health IT. There is a requirement to report Section 907 on basically demographic representation in clinical studies.

And so we issue all those reports, but those aren't guidance documents. But they oftentimes can lead to guidance documents. And I think that's a very important additional process we sometimes to use to get even commentary, participation, public input, beyond what we get just following the requirements in 10.115.

Okay. The purpose of guidance. And this should be very familiar, and perhaps it seems so obvious, not even mentioning. I'm going to mention it anyhow. The first three bullets you've seen if you read CDRH guidance documents. The idea is that when we issue guidance, it promotes transparency, so you don't just have someone standing up at a podium and telling you this is CDRH policy. You actually have a draft and a final, and you see how the policy -- you see to some extent how the policy is developed. And you know that that document actually does represent, and should represent, the policy of the Center or the Agency.

Consistency. So, you have a written document. You don't just have perhaps one branch chief saying, well, this is how I think I'm going to apply my authorities to this application. Then your competitor is submitting a

very similar application to a different reviewer and perhaps having a very different experience. There's a written set of guidelines, and folks should be following those.

And predictability. Again, closely related, but you can read a guidance before you have any interaction with FDA, and you should have some sense what you're going to get.

I wanted to highlight a fourth point that perhaps isn't discussed as much when FDA talks about the purpose of our guidance program, but I think it's very important to our stakeholders. And that's the idea of due process. You may not like where the Agency comes out in a guidance document, but you should have an opportunity to participate in that process, particularly if it's something that's going to be affecting you. And I think we'll be hearing a lot today about the idea of due process and how folks can participate meaningfully in statements of policy that after all do have a very significant effect on our regulated industry, as well as on just the general public.

Interest in guidance. And, again, let me just go over this very quickly. I mentioned from that 1997 legislation that was when we had 701(h). It sets out the basic principles of guidance. 701(h) was actually amended in FDASIA 2012. Just a small provision related to Notice to Industry, and directing us to be mindful that if it's guidance, it's guidance, and we have to use guidance procedures. And by the way, we never intended to

circumvent the guidance procedures with the Notice to Industry proposal, but that was perceived by some to be an effort to do an end run. But that's the significance of that legislation.

Let's talk a little bit about 510(n)(2). It's an interesting provision. Many of you are very familiar with it. And that's a provision that says a number of things about how FDA is to develop policy concerning 510(k) modifications. And one of the things the provision does is it nullifies a draft guidance. It purports to nullify a draft guidance. And I'll just put on the table -- and this is my view, folks might feel differently -- having in legislation a provision that nullifies a draft guidance really does send a possibly not very helpful message about the status of draft guidance.

So, I'll just put on the table, I was troubled during FDASIA that this was not the only provision that was discussed, I think it was the only one that made it into law that purported to affect the status of a draft guidance. It's not unthinkable to me that that could come back in a litigation context or another context to have some ramifications that folks weren't hoping for at the time. I'll just put that on the table.

But, in any case, it does show the level of interest folks have in the guidance program, legislatively and otherwise, and of course stakeholder interests. We do hear from our stakeholders quite a bit on some of the things that are in the air right now. The status of drafts: Are we appropriately treating drafts as drafts, meaning they're not final policy, or are there some

instances where folks are not doing that? Timeliness. Are we finalizing our draft guidances in a timely manner? Participation. And we hear a good deal about the website, and we will talk about that a little bit. Folks know that there was a time when the guidance website was organized very differently, and there'd be I'd say less than enthusiasm about the current organization.

Okay. That brings us to the workshop. We've heard a good deal from our stakeholders, and the workshop really is an effort to air some of these concerns and interests and to have more of a public dialogue about the issues that we experience and that also you experience with the guidance program. And, really, there are three parts to the workshop. We're going to talk about the development process. We're going to talk about best practices, and we're going to have a number of stakeholder perspectives. And then we're going to talk about guidance priorities and priority development.

Workshop goals. I'm going to try to be modest about our goals for the workshop. This is something of a trial balloon, haven't done it before. I think it can be very helpful, but like you, I'm sort of sitting back watching and waiting and seeing what comes of it. What I do hope is that folks feel like they understand the guidance development process a little bit better, understand our challenges, and also understand how the process -- we understand how the process can be challenging to folks who are affected by it, affected by the output.

Promote dialogue on guidance process improvements, and generate ideas for assessing the impact of guidance. This third bullet is very important. And I'll talk about it a little bit when I present on best practices later. We're just now getting to the place where we might be better positioned to actually start developing metrics for our guidance program. And we're not completely there yet, but it's certainly a conversation I want to at least begin having.

So, with that, I'd like to turn things over to Ruth Fischer, who is someone who's a policy advisor at CDRH. And she's just been incredibly instrumental to me in keeping the guidance program moving and on track. And she's going to present on the CDRH guidance development process. Thank you.

MS. FISCHER: Thanks very much to Nancy. This may be the first time that some of you have heard my name or seen me, so I'm going to give you a couple of personal points about myself.

I'm a former concert pianist and college professor. I was a congressional fellow, but not in music, although I do think they could use some music therapy in Congress. I have an extensive background and I am academically trained and experienced in health policy analysis. I've worked for nonprofits and think tanks. I have worked in the private sector, and FDA is my second to last stop, but I have no idea what the last stop might be. I've been here for a number of years. I'm 95 years old.

(Laughter.)

MS. FISCHER: And I am passionate, passionate about baseball and football, and I have the same passion for guidance. I have been working with guidance documents with FDA in various capacities for over 10 years. And I've seen it through -- well, not the beginning, but through several metamorphoses. And what I would like to do in this presentation is tell you about CDRH's guidance development process. I'm going to hit two big points that I think will be ripe for discussion in the panel presentations. And I can't even get off the title page without addressing one of them, which is guidance development.

We are talking about guidance development. I think ask if it has a single commonly understood meaning; I don't think it does. In my own experience, the meaning of guidance development seems to shift according to the context in which it's used. And so that can be very confusing if we have two, three, four different interpretations of it. It gives us this kind of conversation. And I think guidance development is -- and what it means, and what it means to our stakeholders is a really important point that probably could use clarification and may be well discussed with your participation.

So, right now when I'm talking about guidance development, CDRH's process, I'm talking about a standard operating procedure. This is our roadmap for how we get a guidance through all the hills and valleys that go along, and there are many until it is finally issued.

So, there are seven stages. And when I say initiation, I don't mean that somebody has a good idea, wakes up one day, and starts a guidance document. There may be a lot of advance thoughts going on in the Center before internally we actually start beginning. We gather ideas from you. We look at recurring problems. So, it's not just the incubator stage, all right? But in many cases that's already happened.

Then we go onto document development. And I deliberately named it document development so we just don 't get confused with guidance development. And the high points on this slide, I want you to really pay attention that there's a review process, and there's a clearance process. And they're not the same. And, finally, we get to issuance and posting on the web.

So, to get a guidance into our system, every author has to fill out a Guidance Initiation Form. It has to address what the problem or issue is and how the guidance is going to fix it, and what is the urgency of the problem. Urgency can cover a variety of topics and mean many different things. We may have a statutory mandate to get something out. We may have a court ordered mandate. There may a public health problem of such importance that we have to drop everything and start on this. It could be a pressing problem that industry needs direction in. There are many factors surrounding urgency.

Many guidances have people participating from multiple

offices. Now, if you're doing a device-specific guidance and it stays in one office, that simplifies things. But more and more of our guidances are involving multiple offices. And so, any office that is contributing significant resources to this document and its lifecycle needs office level approval. And then finally -- clearance rather. And then finally it comes to the Deputy Center Director or her designee, and the decision is made can we go ahead or not.

A guidance, again, usually it just doesn't emerge out of the clear blue. Although this is -- we're talking about development. People have been talking to each other already, so that's like the beginning of a working group.

And then we have this Good Guidance Practices representative. Well, what is that? In 2011, our Associate Director for Policy, Phil Desjardins, spearheaded an effort to finally put down on paper what our standard operating procedure was. And at this point, although we had a GGP representative before, the roles had changed very significantly in the new SOP in 2011. And this person is supposed to develop high quality, timely, accurate guidance documents. The person is a quality control for the development process throughout its lifecycle and a gatekeeper for formal review at the Office and Center level.

Now, we get to the clearance process. And this is internal to CDRH. The GGP representative has to sign off that the guidance is accurate to

the best of the person's ability, that if we're citing regulations or if we're using mandatory language that there's a regulatory cite along with it, that we're not saying you must do this, but you should. So, the language of guidance has to be correct. Then it goes through Branch and Division review. It goes through Office level review, and then it goes to the Deputy Center Director for Policy's review.

What happens here? I call this the start of the flexible band process because we go back and forth from these -- people have a lot to say in review, and they come back with management perspectives. And I don't know of a guidance document that has never been revised after any level of review. So, this process could be like this, if it's not too controversial, or it could be like this. It goes back and forth. It's dynamic. And that's why it's really hard to pinpoint time frames.

And then it goes to the Regulations Staff, who continues the process. The majority of our guidance documents have to be reviewed by the Office of Chief Counsel. Chief Counsel always has something to say. And the working group will need to revise the guidance after that first legal opinion is given back to us, so, again, flexible band.

A number of our guidances are issued -- you may have noticed in the past that we do an awful lot of joint guidances with CBER Biologics because they have a slice of medical devices. So, if it's sponsored by two Centers or more, we need that Center review. This is review, review process.

Okay. Now, the guidance has been revised many times. Now we're ready to clear it. That means put it on the road to publication. Depending on the review process, and the comments received along the way, this should be ideally everyone has seen this guidance document before. It's not fresh news. You know, no one should be surprised. It should be a faster process than review. It depends on how much revision has gone into that document since any level of review last saw it, so, again, flexible band. And some of our managers not too pleased when they see what they originally signed off on, it's now different, and it's -- because of the legal opinion or other broader Center or Agency policy considerations.

We do the exact same clearance as we do for review. So, it goes to the Office of Chief Counsel, other Centers, if applicable. We have the Paperwork Reduction Act, and if the guidance contains any new burdens for the public, or if it uses burdens that have been previously approved that they're currently in effect, it has to go through the FDA Paperwork staff. And certain guidance documents have to be reviewed by the Office of Policy. And Leslie Kux is going to tell you a lot more about that.

She will also go into whether or not the Department of Health and Human Services wants to take a look at it. And this could consist of many agencies within DHHS. Now, as we're going through these layers of review, not that many are getting to the Department level, or the Office of Management and Budget, but some very key guidance documents are slotted

for review, but not the majority at that level.

And there's a publication process. Editors have to prepare it, have to prepare the Notice of Availability. We have to get on the *Federal Register*'s calendar, and we have to get the guidance prepared to post on the web. The official issue date, even though it is sometimes displayed a day or two or so before, is the same day as a Notice of Availability publishes in the *Federal Register*.

Then we have the public comment period. And a standard time is three months. And I could tell you that most of the comments come in on Day 90. And we also still have to wait because if it's postmarked on Day 90, that's fine. So, if it's postmarked before midnight on Day 90, then we have to wait till it comes in and is processed through our Division of Dockets Management. And then we begin the analysis of public comments.

Okay, the analysis of public comments. Well, talk about a flexible band. One of the first guidances I worked on had 4,000 comments. It takes a considerable amount of time to document every comment, proof it, make a decision, and document the decision and the reason why. It could be very labor intensive. And we consider the comments very seriously. I know that from a personal point of view. The staff gets a pretty bad rap often in the press, and if you had one bad experience with a person at FDA, we're all lumped into the bad apple group. And that just is not the case.

People here are very passionate. They're not all superb, but

they're -- I mean we have -- you don't know the seriousness and the dedication with which people analyze these comments. And they don't do it in a vacuum. There may be a working group of people working on these comments, debating back and forth, what can we accept, what can't we accept, and why.

After that, we're still in the guidance lifecycle. And now we start the final process for a Level 1 guidance. And the only difference is you don't have to initiate it because it's been initiated. And we go through the exact same process on a final as I described for the draft.

Now, what are CDRH's best time frames for Level 1 guidances? I've heard many things about our time frames that don't have to do with numbers. A comment I will never forget came from an advisory panel meeting, and the surgeon said to me about this guidance, he says, this is like watching a glacier go by. And it seemed like that. But if the stars are aligned, the moon is in the seventh house, we have the dawning of the age of Aquarius, drafting a new guidance document -- after the prep, when we actually start that initiation process, the best time we can do is probably 14, 15 months. Analyzing public comments depends on how many comments we get.

And don't forget, if you take 90 days and you don't get your comments all together until Day 100, we've used up three months of time. All right? And then the clock starts ticking again. The best case scenario for

finalizing a new document, a new guidance document would be a year. Do we make this all the time? No, but this is what we're striving for.

And I hope I've given you just a little flavor of what is involved inside CDRH so that you can better understand what takes time. You know, I didn't come from the federal government. I used to ask how could they possibly be working on this for so long? And then I got here, and now I understand. Can we do better? We can always do better. I mean life is about continuous improvement, so we have a continuous guidance improvement process open also.

We want to hear from you, and we hope that the afternoon panel discussions can grapple with some of these issues and bring them to our attention. We're open for your honest comments, and I say that sincerely. Nancy Stade is very sincere about wanting you to be honest with us, and we'll be honest back. We need personal relationships. It's not industry and FDA. It's people in industry, and it's people at FDA. And if we get to know one another better, we can solve our problems a whole lot easier.

I really thank you for your time. The small potatoes portion of the program is now over, and we're going to the heavy hitters. Back to Nancy.

MS. STADE: All righty. With that, the next part of today's agenda is going to be presentations on guidance practices.

MS. FISCHER: Nancy, I forgot my second point, which was --

MS. STADE: Do you need --

MS. FISCHER: Just a tad. All I wanted to say is guidance development is misunderstood. Guidance document means it's not a standardized widgit. That's what makes it so difficult to try and put, you know, regimen and time frame.

MS. STADE: Thank you.

So, I said it provokes a lot of passion, the guidance process, and I think you saw a little bit about that internally. And I hope we'll see more also from everyone else outside the -- on the outside world. This is a judgment free zone, so feel free to share your most, deepest, most passionate feelings about the guidance program.

All righty. So, as I was saying, the next part of the agenda is going to be on guidance development -- on practices for guidance development. And I'm going to talk a little bit about CDRH Good Guidance Practices. Really what I'm going to talk about is, you know, what we're doing and also how we're doing. And my hope with this presentation is to set the stage for the discussion later today, both on whether there's more we should be doing, and if so, what that is. But this will at least give you a flavor for what we have been trying to do with our program.

And so, this is a working definition. I didn't pull it from anywhere. I kind of made it up, but I don't think it'll be too controversial, just

the idea that what is a GGP practice? Well, let's use this working definition, if folks can agree to it. Practices that when followed will most often produce high quality documents ensure appropriate participation from external and internal sources and make efficient use of FDA's and stakeholders' resources. And I'll point out what probably should be obvious, which is that the first two bullets can be somewhat in tension with the last bullet.

So, we want a process that's efficient, that addresses the timeliness interest we all have in the guidance program, but we also want one that has good processes that ensures due process for folks who are affected by our guidance documents, and that also ensures we have quality documents. That's very important to me. I think it's very important to everyone who's involved in this process, but it is a little bit in tension with this other interest in efficiency.

I'm going to share with you the challenges we face, and let me walk through these a little bit. I think these are the three big buckets of challenges that we face with guidance development. The first, of course, is resources: too few and many other priorities. And, you know, I'm not whining really. But CDRH's program is resource poor. It just is. And that's -- you know, you can be very scientific about this and compare the FTEs and also the output to other programs in the Agency. And by the way, I do think guidance programs elsewhere in the Agency would probably also say that they feel that they're resource poor.

We're resource poor. I think we're getting better because we've recognized that we just -- if we take this seriously, we need to put more resources into it. Also, we have had dedicated MDUFA resources for our program. But still, we're still thinly staffed and, as you know, CDRH is -- we have many other things we need to get done. It's not just the guidance program.

The second bucket of challenges, conflict, by that I mean -- and I think Ruth demonstrated this very deftly and very colorfully in a way that I think will stick with people. Folks disagree. Folks disagree where we should come out. Their policy goals, some folks think we should have different policy goals. There can be differences in opinion in different layers of the organization. At the review level, folks may see things very differently from at a different level in CDRH, and there might be differences of opinion between the higher levels of CDRH and other parts of the Agency or other Centers.

And then, of course, our guidances go out for comment, and sometimes we find that there's a whole other layer of conflict. And that's just a fact of life. I don't think we should run from that. That's just true. People think we should come out different places. These are important documents, and I obviously will be making that point over and over again. But part of the reason the guidance program is such a bear is because it does something very important. It announces how we're going to be implementing our

authorities. And people have differences of opinion.

So, the last bucket of challenges are the process, and I hope you took the flavor from Ruth's presentation that, yeah, it's not without complexity, the process. You know, I have to own up to that. We have done a lot of work on our process. It was complicated before we started doing that work. It's complicated now. And, again, that goes back to what I said before with best practices. There's this tension between quality and efficiency. And sometimes to get the quality, you know, you need to build more processes in and you have to sacrifice some efficiency. And we're where we are with that.

We have a complex process. On the other hand, we do have a written process that I think folks are beginning to understand within the Center -- beginning to. And then, we do have some legal constraints on what kind of processes we can engage, how we can engage with people when we're in development, and also just the basic process. We have to follow our GGPs.

And let me just put out a hypothesis here. I mentioned before that a lot of times when people talk about guidance, and internally or externally, they, let's say, grouse about guidance, they talk about the guidance process. I actually think if you scratch the surface, a lot of times you get down to the first two buckets: resources and conflict. I do think internally, probably even externally, a lot of the sources of concern about the guidance process have more to do with internally we don't have enough

people dedicated to it, and it becomes very stressful.

Externally, people don't always like where we come out. And, again, I don't think we should run away from that. I think that's probably something that's going to happen when you're dealing with something that's so important. You know, the question is how do we best air those conflicts to the extent we can address them and still move forward producing quality documents in an efficient manner?

Okay. This is a very complicated slide. I don't know what it means exactly, except the bottom line. It's something someone in our guidance program developed, and it was a study in 2005, before I was with CDRH. But the intention was to analyze -- when you look at all the guidance documents we develop, and all the time reporting that goes into our time reporting system, about how long does it take to develop a guidance document? And, again, I can't really vouch for what all this says, but I'm told when you add it all up, at the end of the day what this says is it takes about one FTE to develop one guidance document. That's on average. Obviously, some will be more, some will be less. That's average.

And here's a little bit more of a straightforward analysis, again, showing the time reporting. We have in fiscal year 2012 about 42 FTEs to produce 31 guidance documents, or about 1.3 FTE. And I gather this is just within CDRH, so it's not counting all the external reviews that go into our guidance documents. The ultimate FTE would be somewhat higher. But it

shows, again, these both show you basically, you know, we're talking about one FTE, maybe a little more, to develop one guidance document, and that's just CDRH resources.

So, now I'm going to talk -- my slide is missing a header, but this is intended to show some of the activities we've done in recent years to improve the guidance document, again, to achieve these goals of efficiency, quality, and participation. And the first thing we did in 2010 was to develop and pilot written SOPs, standard operating procedures. So, folks who were operating within the system knew how they were supposed to do it because I can't tell you how nontransparent -- how challenging it can be to have a complicated system where there's no written record of what you're supposed to be doing next.

So, as Ruth described, while guidances go through these levels of review, the process isn't written, and you might not know where it goes next. And, in fact, we saw that happening. Guidances were just sitting because folks would finish their review, and they had no idea where to put it next, so it just sort of sat around. So, that was helpful. I think it was also helpful and educational in seeing just how many steps there are involved, if you're doing this properly.

So, and in 2011 they're updated and finalized. And those are the SOPs we have in place, but we do say, you know, these are living documents. They are always open to change, to improvement. You know,

we're open to streamlining them. We haven't really figured out how we do that without sacrificing the other pieces, which have to do with quality and participation.

2012 -- and this is big -- we developed a guidance tracking system. And so I said we're very interested in thinking about metrics. How do we measure how we're doing both in the guidance process and then also in the usefulness of our guidance documents? Certainly for the process, and maybe to some extent for the usefulness also, you know, we need to have some tracking system. And so, that was rolled out in 2012, I'd say widely put into use 2013. And so we're starting to have data. And I'm going to share some of that with you. But, again, it's very preliminary because the guidance wasn't -- the tracking system wasn't widely used until 2013. And that's -- the tracking system itself is always subject to additional improvement. But I do think this is going to be critical in helping us improve our guidance program.

One of the other things we've done over the course of the past five years is to somewhat centralize the guidance program. And I wouldn't say we have a terribly centralized guidance program. You think of devices and how different one device is from another, I'm not sure it makes sense to have a completely centralized program, but we have it somewhat centralized. So, we have -- our offices have guidance programs. And particularly the review offices, which produce quite a few guidance documents, have their staff dedicated to guidance.

And then we have -- in the Office of the Center Director we also have staff working on guidance. And when I say staff working on guidance, we have a number of people who have some -- you know, less than 50% of their time, probably 20 to 30% of their time is spent on guidance. We do not have many people who do all guidance all the time. But certainly we have more than we had.

Okay. And so we've also piloted -- we've also started to take some new approaches to guidance documents. These are a few things that we've been doing in CDRH, or we've started doing, or we intend to be doing a little bit more. And one is the idea of the leapfrog guidance document. I'm not sure if you've heard the term, but that's the idea of a guidance document that actually tells you how we're going to -- how we propose to review a technology when the technology is not even in front of us yet. And so we've done with some of the -- with the artificial pancreas guidance documents. And I anticipate we'll be doing that in other technology that we expect to be coming in the door. It's not in the door yet, but we can help encourage folks to develop that technology by telling folks how we expect to review that.

Level 1 Immediately in Effect premarket guidance documents. This is related to the Notice to Industry. As I mentioned, there is something in FDASIA about that saying Notice to Industry will follow guidance processes. And this is -- we've developed a process saying, yes, we will follow the guidance process. There is a part of the 10.115 that says in certain instances

it may be appropriate to do an Immediately in Effect Level 1 guidance. And what we've said is for certain premarket issues, what it's really important to let you know that we're going to be asking for something that we weren't asking for previously, we'll do a Level 1 Immediately in Effect premarket guidance document.

And we haven't issued these yet, but we've provided notice that we have an SOP in effect to allow us to give this notice quickly and, indeed, to have an opportunity to consider the value of -- and comments on that approach while the approach is in effect, and perhaps to revisit it. But in some cases, it's so important to get those recommendations out there that we would do it with a Level 1 Immediately in Effect.

And then this other thing called short-form guidance documents we think could be very helpful for updates. And we have heard -- and I think it's a fair statement -- that we're not always doing so well with updating guidance documents that have been out there a long time. And so we've developed a more streamlined process for short-form guidance documents that are short, and they're generally intended to update some aspect of an existing guidance document. That's not the only use for the short form, but that is one way we anticipate these guidance documents to have a more streamlined approach to get more current information into guidance documents that are already out there.

And so here's some supplemental processes. So, I've said

10.115, 21 C.F.R. 10.115 sets the baseline for the processes we have to follow when we're developing guidance documents. It doesn't mean we can't do other things, and we do do other things in certain cases. Now, you can argue, or you can certainly tell us whether we've used these processes appropriately. But I think it's worth at least laying out some of the processes we have used, some of the arrows in our quiver, if you will, to see how useful these can be.

In some cases, we open a public docket even before we issue a draft. So, we did this with custom devices because we had new authority in FDASIA, and we also were on the line for producing a guidance within two years of FDASIA. And we wanted to know more about what folks thought about this provision: how it would be used, how folks -- both physicians and manufacturers had been challenged by the way the previous provision had been implemented, when a custom device exemption would be particularly important to get devices to patients who need them. And so we opened the docket before the draft.

And I'll just say, from my experience with that and otherwise, you know, so we've had the experience with custom devices. We did a docket that we issued a draft guidance. We sometimes find the commentary is more helpful when folks are responding to a draft. I don't think that's surprising. It gives people something to react to. And people tend to be very articulate when they really don't like something, or when they really do like

something. And sometimes when they're speaking in the abstract about what they might like to see, it's not quite as informative. But still, I think it's a useful tool, particularly when you're looking for just very general background commentary on an area where you think you might be developing guidance documents.

And then, of course, when we do our annual prioritization the beginning of the fiscal year, there's an opportunity for folks to comment on guidance documents and on our guidance process and on suggestions for prioritization.

We have workshops and panels, device specific. Occasionally, when we know we're going to be developing guidance in an area of technology, we do hold workshops to discuss what might be appropriate review -- what might be appropriate information in the review of that technology. And then we have policy-related workshops and panels as well.

Pilot programs, whether before or after a draft guidance document, we've done this occasionally. Of course, with the parallel review pilot with CMS, we said at the outset, you know, at some point that might be an area where we develop guidance. Right now, we're going to pilot the approach.

Formal and informal discussions at conferences, meetings, et cetera. And something we've done with several guidance documents is we have stakeholder calls or webinars right after something is released. And

that's an opportunity to explain it a little bit more closely than what you'd get from just reading the guidance or from reading the FR notice, and also to ask very specific questions.

Okay. So, here's just a little bit of data on how many guidance documents we've issued in the past five years, CDRH. And let me say, we do actually for this have the data going earlier than 2010. And without getting into it, I'll just say the numbers were smaller. And that's, you know, in part from centralizing developing processes. The activities I spoke about before have actually borne fruit in one sense in that, yes, we do issue more guidance documents. If you look at 2012 -- now the data here is how many guidance documents were actually published in that year.

So, it looks like 2012 was a dip. In fact, you know, I think if you're looking at guidance documents that emerge from CDRH, the number would be much flatter, right around 40 to -- I 'd say high 30s to low 40s range. But in that case, for whatever reason, there are guidance documents that then didn't emerge to publication until the following year. And then you see 46 in 2013. Well, let's just say we're doing high 30s, low 40s, with some consistency.

And this is a little bit of information on what we're issuing: cross cutting versus device specific. And as you can see, we're tending more towards the cross cutting. And when I say cross cutting, that means like policy documents. It can be something on a particular -- on the PMA program

on a particular authority that cuts across different product types, versus a device-specific guidance document, which might be -- tell you very specifically what you need to submit in a particular in vitro diagnostic -- in an application for a particular IVD test or something like that.

Draft versus final. You know, again, and give where we are, it would probably be nice to see each year a little bit higher on the draft side than on the final. And for the most part, you know, maybe -- in 2011 -- or, I'm sorry, 2013 is an exception. For the most part that's where we are, but it's not perfect. We're issuing a lot of brand new guidance documents, in addition to finalizing drafts. That's how it breaks down.

The last slide, I told you that beginning in 2012, and perhaps more -- we became more serious about it in 2013 -- we implemented a tracking system. And we expect to have a lot more data about our guidance program as we move forward using the tracking system. But we are starting to get some data back. And this slide tells us -- now, I just want to give a little bit of a disclaimer because it's not perfect. And we only have data for guidance that's in the system. So, in other words, for a guidance that was in the system both when we initiated it and in the system when we finalized it.

This won't show guidance documents that have yet to be finalized, and it won't show guidance documents where we initiated the draft before the system was running. And this does go to 2007 just because in some cases we actually have that data, even though they weren't in the CTS

system. But, again, the data's imperfect, but it does tend to show we're getting a little bit better at finalizing draft guidance documents. And I'll say, I do -- this is my perception -- I believe this is the case, but we're trying to do a better job on this.

So, with that, that concludes my remarks on the CDRH guidance program. Again, there will be an opportunity for some questions and answers after we finish the stakeholder presentations.

But, right now I'm going to ask Leslie Kux to come up and to talk about guidance practices at the Agency level. And this is our Assistant Commissioner for Policy.

MS. KUX: Thank you.

Hi, everyone. I'm Leslie Kux, the Assistant Commissioner for Policy. And the Office of Policy sits across all of the reg programs and guidance programs in the Agency. We're the final stop in FDA for the documents, and we do a final clearance on them. And then, if they're going to be -- if they're going to go into external review, we're the Office that manages that with the Center.

And I'm going to talk about the Agency-wide considerations and perspective with respect to developing guidance because obviously CDRH, as you've heard doesn't exist in a vacuum. And so, there are outside of CDRH considerations that need to get taken into account. And I thought it would be useful also just to give you a little bit about my background so that

you can understand sort of why we have this perspective.

So, I started at FDA a lot of years ago, and I was in the General Counsel's Office for a number of years. And for part of that time I actually counseled CDRH in the early '90s. After Chief Counsel, I went to the Center for Biologics, where I was in the Office of Compliance. And the Office of Compliance has actually both a compliance function but also has a review and inspection component. So, I was -- working at CBER was able to sort of see guidance from both a compliance perspective and a review -- you know, an application review and inspection. And we worked with CDRH a lot.

And then I came to the Office of Policy as the Assistant Commissioner for Policy, and one of our responsibilities is cross-agency coordination and the external review. So, one of the things that I'm interested in, or my Office is interested in when a guidance document shows up, is to make sure that all of the cross-agency considerations have been taken into account, and that the policy considerations have been appropriately addressed, and that if there are any discussions that need to take place in the Office of the Commissioner, or with the other Centers, that those conversations happen.

So, I thought I would give you an overview of the entire process with a graphic just to show you what all of the different guidance steps are. It's not a -- and I'll talk more about this later -- even though guidance is not a rulemaking, they're still very significant documents from the Agency's

perspective. And so, all of these steps have been overlaid on what people thought was probably going to be a fairly straightforward, simple, fast process when we were doing it back in 1997. It is faster than rulemaking, but it's still a process with a lot of steps, as Ruth and Nancy have already pointed out.

A couple of things that I wanted to highlight because they may not be so obvious to you, but they do add -- can add considerable time to getting a guidance done, is the Paperwork Reduction Act process. This is a process separate and apart from any other clearance process that requires the Agency to get paperwork, what we call paperwork approval if a guidance document has reporting or recording keeping requirements, or third party disclosure requirements like labeling. And that process involves a separate interaction with OMB that can add a lot of time to a guidance document.

So, keeping that mind, and wearing everybody out before I get to the next slide, I wanted to talk about what our considerations are. And they echo a lot of what you've already heard and that you'll continue to hear. But it's really important I think for folks to understand that from FDA's perspective, a guidance document is our official position. It's something that people can rely on. And so it's very important to us that it be carefully thought through and technically sound.

We want it to be reliable. We also want it to be useful, and then we want it to be consistent with other Center guidance and then across

FDA. As Nancy's already referenced, we want it to be legally sound. And then we also want it developed with stakeholder input because that contributes significantly to its utility and its reliability.

In fact, when I first got in the Office of Policy, as part of the transparency initiative, we did -- we pulled together a group of folks from across the Agency to look at best practices around the Agency. And for those of you who deal with other parts of FDA besides CDRH, you'll already know that every part of the Agency is very different. Every Center has its own approach to the way it handles guidance documents and just about everything else. And so, they're a really wide range of best practices around FDA because each Center and sometimes each Office has to tailor its guidance program to its own needs.

But the common best practices across FDA are to have a clear approach to initiating a guidance. In other words, we're trying to avoid situations where somebody in an Office thinks that a guidance is a good idea and starts working on it without making sure that Center leadership, and if necessary, Agency leadership, agree that that's a good use of Agency resources. But even once everybody agrees that a guidance document is a good idea, we will need to prioritize them. And this, I think you'll hear, you know, is one of the most challenging aspects of our work because we don't have all of the resources that we could use.

You've already heard Ruth talk about what happens when a

document's being drafted and when it goes into FDA clearance. But we also have best practices to try and make the drafting process efficient, and the clearance process efficient. I think it can be difficult when documents go to other Centers to make sure that their level of priority is maintained, if that Center is grappling with other issues. And that's one of the areas that the Office of Policy can help is to, you know, to make sure that people understand that something's not only a Center priority, but also an Agency priority. And so that's something we try and help with.

And when it comes to external clearance, as folks have already said, there are documents that are significant enough that the Department of Health and Human Services or OIRA wants an opportunity to review them. It tends to be documents that are of a very high profile for a variety of reasons. It might be because the issue that they deal with is a very significant public health issue. It might be because it's perceived as being particularly controversial. It can add considerable time to the process for getting a guidance document out because we're dealing with people who aren't familiar -- who may not be particularly familiar with that program area.

And so we often have -- you know, part of what we do is -- part of what we have to do is an education process as well. Sometimes they've already heard from stakeholders with concerns about the guidance document. And so we need to make sure that a full picture is -- you know, that our side of the story, for lack of a better description, gets presented as

well, and that the folks that are looking at the document have a full picture and understand why we think that guidance document is appropriate and necessary.

As, again, CDRH has already talked about, outreach is really important both before we begin drafting and then once we have a draft. If a document makes it through all of those hurdles and a draft gets out, you know, we really do want input on the guidance document. It's not -- I've never met a guidance document that didn't change because of comments in one way or another. Comments are always useful.

And it may not, it may not feel like that when people see a guidance document, but just from my more than 20 years at the Agency and involvement in at this point probably hundreds of guidance documents, comment are always, always useful. And we go out of our way to make sure that we get them from whoever is interested. And the amount of outreach that we've done has just increased exponentially over the years, and the Internet has helped tremendously with that.

We also have best practices around finalization. Different Centers have different approaches. Some look at the comments, and if they're really -- if what the comments suggest are sort of some technical -- if it's a very technical document and the comments are really technical in nature, they don't raise significant policy issues or significant legal concerns, then, you know, some Centers will try and just push those through very

quickly and, you know, may try and expedite the review process, the FDA review process because of the nature of the comments. But, otherwise, we go through a very rigorous process of looking at the comments and discussing them and trying to figure out sort of what the right balance is for the guidance document.

And then we also have implementation processes to make sure that we're reaching out to stakeholders so that they're aware of the guidance, and that if it's a technical guidance where we expect industry to -- or other stakeholders to be actually implementing it, and then we -- and our, for example, inspection force to be also familiar with the guidance, we'll do both industry and internal training.

As an offshoot of this exercise, we've been doing work around the Agency on some of the concerns we heard. One, people have already referred to. It's very hard to find guidance documents on the Agency's website. I can't even find them, and I should know where they are. And so we are working with our web folks to figure out how we can create better repositories for guidances. And also, it turns out, something as simple as how we name the guidances can make them easier to find as well when people go to the Internet to search for them. So, we're trying to deal with some of those. We also -- as Nancy says, you know, we do internal reviews to look at how well we're doing and figure out if there are things that we can do to streamline to our processes.

I thought it would be good to spend a fair amount of time on opportunities and challenges because one of the reasons I'm so glad that CDRH included me in this is this is an opportunity for me to hear from stakeholders what works, what doesn't work, what you would like us to do better or differently. And then I can -- and it gives -- you know, I can take what I hear here and think about it in the larger Agency context. And stakeholder engagement is one that the Agency struggles with a lot.

Despite the amount of stakeholder engagement that we already do, we always hear it's not enough, and we always hear that people would like us to approach it in other ways. I think we hear a lot -- I hear that people don't -- you know, people want to sit down with us. They want to have specific conversations about specific guidance documents. And I think the -- or a guidance documents comes out and they want to have a meeting. You know, a particular stakeholder wants to come in and talk about it with us.

You know, our challenge is how to get the best input possible, but also maintain the appropriate level of transparency and make sure that the comments that we receive are public and so that all the stakeholders have an opportunity to see the same thing. And so I'd be very interested in hearing from all of you what you find most effective, and if you have suggestions about how we can work with all of you better. And what I guess are -- why is there -- and it's not just with CDRH.

We hear it, you know, we hear it in other program areas as

well. Why is there a desire to just sit down one on one? Why isn't a public setting -- what are the concerns about a public setting or what are the considerations that go into preferring a one-on-one meeting, which as I said is pretty difficult for -- I mean, it's something that's very challenging for us.

And then the draft -- you know, trying to finalize drafts and the tension between resources and the demands on us to get out new guidances. I'm trying to think -- since I've come to the Commissioner's Office -- well, I came right after the Tobacco Control Act. There was FSMA, FDASIA, the Drug Quality and Safety Act, all of those -- maybe not for CDRH in particular, but all of those reflect a significant new workload for the Agency. And FDASIA certainly did for CDRH. So, as we're issuing draft guidances, we're also getting assignments to write new draft guidances. And how do we keep up with getting out the new drafts and finalized drafts at the same time?

And also I think there's a -- I think people would like us to finalize them faster, but we also need a certain amount of time for reflection on the comments. And sometimes the comments raise really, really challenging issues, and what's the right balance between reflection and speed. Even if we had all the resources in the world -- and maybe one we will -- you know, all the resources we think are necessary, there would still be a certain amount of time that we would want to spend reflecting on the input that we receive from people and what's the -- sort of what's the, what's the right amount of time for that.

And then, you know, priorities and resources are constantly shifting. It's just the way we live. And what was a priority a year ago gets overtaken by -- can get overtaken by any number of situations. And how do we balance the constantly shifting priorities while keeping track of the things that have sort of fallen off of the current priority list? And so, some of -- I don't have any more slides, but I did have some questions that I wanted to put on the table, and we'll have an opportunity for discussion later.

And Nancy has sort of started me thinking about this. CDRH is very thoughtful in its guidance program and has really -- I know has done a lot of work thinking about ways that it can be more efficient and also be effective. And it's hard not to think that the guidance process has become a little -- you know, becomes every year more and more like the rulemaking process, which people have already said is ossified and broken.

And so what can we do in the guidance area to make sure that that -- that it doesn't get worse, number one, and two, that it actually becomes a little simpler? Because I think everybody recognizes the utility of guidance. And plus everybody always seems to want more of it, which is why I think it must have utility. And I wonder do we need a new type of guidance that's sort of guidance light that falls someplace under guidance? It's recommendations, it's thinking, you know, it's a way to get information out there without maybe holding it, you know, at such a high level.

You know, any ideas that people have for ways that we can get

useful information out there, but in a more timely fashion, I think we would be -- I would really be interested in hearing. You know, from where I sit, I can -- I do see that it becomes -- you know, that there's sort of more expectations and more burden put on guidance sort of with every passing year. And I do worry about whether it'll -- what was a very -- I think what was intended to be a simpler process will sort of collapse under its own weight, and we'll end up having to start again from scratch.

So, if there's a way we can think about something to bring in to the arena that's -- that is -- that does start conversations, that does allow people to share thinking, that doesn't -- that isn't quite so legally significant or significant from a policy perspective, I think that might be something really worth pursuing. And so, with that, I'll stop and turn the program back over to Nancy. And I do want to say thank you again for the opportunity to participate.

MS. STADE: Thanks very much, Leslie.

So, right now we're going to have a break for 15 minutes, but when we come back, we'll hear the first of our stakeholder presentations. So, let's see, we are at -- I'm going to say 10:20, so if you could come back at 10:35, and we'll start up again. Thank you.

(Off the record at 10:22 a.m.)

(On the record at 10:36 a.m.)

MS. STADE: We'll continue with stakeholder presentations.

And we have three stakeholder presentations. And to start with, we have Janet Trunzo, the Senior Executive Vice President, Technology & Regulatory Affairs for AdvaMed.

MS. TRUNZO: Okay. Everybody's coming back in. Great.

Well, thank you very much. I really do appreciate the opportunity to talk about guidance document development and prioritization. And one of the reasons why I was so delighted to get involved in this was that this was one of my first assignments at AdvaMed. I started at AdvaMed back in 1996. And one of my first duties was to comment on a docket that FDA had issued about good guidance practices.

And so we found -- we searched our records in advance of this meeting in order to see everything that AdvaMed had ever said about guidance document development. And the first document that we pulled out was from 1996 that I had actually signed, so this is a topic that is very important to us. And I wanted to be sure that everything I said today represented what we had said in the past on a variety of topics around guidance document development. So, that's my little personal story, like Ruth gave her personal story a little bit earlier.

I was also very intrigued by what Ruth said about guidance, her passion for guidance documents, and I never had heard guidance documents and baseball and football all in the same sentence.

(Laughter.)

MS. TRUNZO: Anyway, today I'm going to talk a little bit about where we have been on the background related to guidance documents, the development process itself, priorities, updating current guidance documents, and ultimately the use of guidance documents.

So, from the AdvaMed perspective, we have always supported the need for guidance documents. And whether they are cross cutting or whether they're device specific, this is an important element of the device review process because the guidance documents provide clarity to our members on what FDA's current thinking. And without that clarity, it is just so difficult for a company to figure out exactly what the FDA expectations are for the submissions and the process around that.

And, therefore, we have always been a strong supporter of guidance documents, and I'm going to give a few examples of how we have supported the development of guidance documents. And, again, they're from my personal perspective of activities that I engaged in with FDA early in my career at AdvaMed. And as I mentioned, the device-specific guidances are as equally important as these cross-cutting guidance documents because they are specific to a device type. And when companies are putting together data for their submissions, the guidance in these device-specific guidance documents are absolutely essential.

And we've always been supportive of the good guidance practices. The document that I referenced in my opening about what I had

signed back in 1996, the gist of that message was all about the need for good guidance practices across the Agency so that there is consistency in how the documents are developed, how they're issued, and how they're ultimately used by stakeholders.

So, I think that was one of the questions about the development of guidance documents from Nancy's earlier talk about seeking stakeholder input and how that is happening. It is so important -- I wrote down all of the various methodologies that were talked about earlier about having an open docket prior to publication of a draft. I think that's a great idea. I think it allows for collection of comments from the public, having public meetings and workshops and meeting with small groups. But getting input from experts is equally important, and using all of these methods to do so are very helpful in getting a quality document at the end of the day.

I think what I didn't hear mentioned today in the development of guidance documents, or perhaps I missed it, is that often there are international consensus standards being developed on a specific issue, or on a specific device type, where experts from around the world get together in a consensus method to develop a standard. And I think those standards are very important in using them in the guidance document itself, especially in these cases where we're looking at guidance on device-specific products where an international standard is very helpful, and references to it, consistency to the standard, is an important part on many levels, not just on

the global harmonization level, but it does provide some technical expertise that has already been negotiated in an international setting.

And then I also like the idea of FDA meeting with the commenters to seek clarification. And we've had a recent experience with Nancy on that where we submitted comments, and Nancy contacted us to seek clarification on those comments. But I think it's -- you know, sometimes even in the written word we're not 100% communicating what we're trying to say. And I think any opportunity where a group could get together, whether it's FDA and the commenter, to understand what each other's trying to say -- because sometimes we may even misunderstand what's in the guidance, and then at the same time FDA may misunderstand what points we're trying to make. So, opportunities to have those discussions are also quite important.

So, I just thought I'd do a little stroll down memory lane. And when the 1997 510(k) modifications guidance -- and this is one that companies were very much appreciative of this guidance. One of the reasons why is it provided a flowchart for coming to the decision as to whether the -- what kind of action the company had to take based on the modification to the existing 510(k). That was one in which there was a lot of interaction between the industry and FDA in developing that guidance, and that was one of the quality guidances.

I'm going to talk a little about the least burdensome guidance. This was an example of a guidance document, and I was -- this was again one

of my assignments back in the early days of AdvaMed, my career at AdvaMed, where the 1997 FDA Modernization Act had just passed, and there were -- it was the first time least burdensome concept was part of a statute. And so FDA came out with a guidance document. It was a guidance document that was written without stakeholder input. It was quite challenging of a guidance document, and we commented on it. And CDRH actually withdrew that guidance and worked with stakeholders to talk about least burdensome concepts.

And the least burdensome guidance that was ultimately published -- and the way it was presented were there were many examples to demonstrate a least burdensome concept. So, they were kind of real world examples. And I think the interaction with stakeholders was very helpful in getting those examples to demonstrate the least burdensome concept, and we always thought that that was a good guidance document.

I thought I would also mention a device-specific document. And I'm talking about the heart valve guidance document. It was published in the early '90s and was further updated because the heart valve guidance document, again, was one where there were interactions with companies and with academia on developing the guidance. Because in this guidance document there were the objective performance criteria, the OPCs, and that needed a joint effort by the companies and by academia in order to come up with the proposal for heart valves. So, those were my three types of

guidance documents that -- I know they're old, but --

The guidance document priorities. I do, from our AdvaMed position, support identifying priority documents for development. I think on an annual basis, with the resources that FDA described earlier, prioritization is so essential. And so, as far as the priorities go, those priority documents in the lists that come out where stakeholder input is possible is very welcome to us, so that if there is a Priority List A, which is the way it is -- we developed that Priority List A, and Priority List B in the commitment letter under MDUFA III -- that should be a dynamic list. You know, things change in the course of the year, so it may be necessary to adjust the priority of those documents.

But in the prioritization process, I think documents implementing the statute, like MDUFA and FDASIA, should be top priority. When the MDUFA agreement was reached for MDUFA III, it established a lot of new things. And FDA was frantically pulling together I'm sure all of those guidance documents. We had eCopy for the first time. We had refused to accept procedures for 510(k)s and PMAs. All of those required guidance documents.

We had established in the MDUFA commitment letter a new process around pre-submissions and how the pre-submission process was going to work, about developing the minutes from those. There were timelines associated with it that involved both the sponsor and FDA. So, those kinds of guidance documents to implement the statute that went into

effect on the day -- on the first day of the fiscal year are top priority, from our perspective. And in the future, if there are new programs established under the law, those documents should have top priority.

But the second bullet here is one that I did want to talk about just a bit, and that is finalization of documents. I noted earlier on the slide that Nancy showed about the time it takes from the moment the document is issued at draft to its finalization, and those demonstrate an improvement over time over the last several years. But I still believe there are a lot of draft guidance documents out there that have yet to be finalized. And knowing the resource constraints -- because if you go on the website and scan through the guidance documents, you'll see a lot that a have a draft notation on them -- is that they also need to be prioritized into which ones need to be finalized first.

The process for updating current guidance documents, AdvaMed talked a lot about this in our commentary over the last many years. We have always believed that an established process for reviewing and updating guidance documents is needed. Once they've gone final, they've been in use for a while, it is really important to establish some frequency around which they should be reviewed and updated. Now, you know, it's easy to say that. And I understand that.

But I don't -- I think the frequency could be based on the type of guidance it is, or it -- because maybe not all guidances need to be reviewed and updated on a certain frequency, like every three years. Maybe some

have the ability to not change over those years, but there has to be some sort of system put in place to ensure that the guidance documents are current. And sometimes guidance documents need to be taken off the FDA website. They are obsolete, they've been replaced by other guidance documents, or sometimes they're redundant to some other new process in place.

These guidance documents, when FDA needs to take these guidance documents off the website, remove them because they're no longer in effect, I believe it is important to notify stakeholders that we are removing this guidance document because of whatever the reason is. And I think that goes to this whole transparency about the guidance process.

And guidance documents under revision should be flagged. And that goes back to if there is -- you know, FDA is changing its thinking on a specific topic, and that guidance may be under revision, and it is a priority, there needs to be some notation for the users of that guidance document to know that maybe they better check with FDA before they proceed down a path.

And, finally, on the use of guidance documents, the one area that we think is so important is that there needs to be training of FDA staff on new guidance documents. I understand that that occurs, so I'm just putting it out there as something that is very important, that everybody is on the same page on a guidance document, especially when it's issued. But this -- so I'm going to -- it might sound a little confusing here because draft guidance

documents should be finalized in reasonable time frames. And I know that there's an effort to do that, but the training should be on the final guidance. The draft guidances should not be used as though they're final.

And then in cases where the guidance document is final and it is in place, and everybody knows what the expectations are, if a reviewer needs to deviate from the existing guidance document, there should be some level of approval of that deviation so that the management within FDA understands that there are -- there's a request from the specified requirements in the guidance document, and that request should be -- there should be a justification for it.

And then I just want to make one more comment about the Immediate in Effect guidance document that FDA issued and SOP about Immediately in Effect guidances under CDRH. And it is -- we were very supportive of how that turned about because Immediately in Effect should only be used in situations where there are public health needs that require it to be immediately in effect that warrant that status. And FDA has established an internal SOP to do just that, to ensure that here is oversight of when something -- a guidance is immediately in effect versus just recommendations.

So, in conclusion, I believe that the GGPs were established to ensure consistency in the guidance process. I think that transparency in the process from its very beginning when FDA publishes a docket even before a

draft is issued, all the way through the process where FDA holds public meetings and interacts with groups and stakeholders throughout the comment process and even afterwards, I think the transparency that the GGPs were intended to provide is so important. And we're very supportive of all of those methods to ensure transparency in the process throughout.

We also believe that stakeholder opportunities in the development of guidance documents at the end of the day will yield a quality document, and that once those documents are in place, that training is so important. And sometimes the documents are so -- could be ones in which the training goes beyond that within FDA and stakeholder training may also be necessary.

And then in all of these regards, AdvaMed is supportive of the development of guidances. We will work with FDA in any way to ensure adequate training or access to experts and commentary during the development of the guidance document. And, again, thank you very much for your attention and the opportunity to give our perspective to today's meeting.

MS. STADE: Thank you very much, Janet.

So, we have two more presentations from stakeholders, and next up we have Ralph Hall, Professor, University of Minnesota Law School, to provide another perspective.

And after the perspectives, we will have an opportunity for

Q&A.

MR. HALL: Thank you, Nancy.

And I'd like to start by commending the Agency for the meeting, for the openness, and also for the work they've put into the material already presented at the meeting. I think the information, for example, on the time from draft to final is fascinating information and provides a lot of meat for us to consider going forward.

Just to make sure people know my affiliations, there they are. And I'll point out that I do work with the 510(k) Coalition, who have helped develop these comments.

One of the things that we want to talk about is, yes, the development but also the use of guidances, and some thoughts on the regulatory agenda. At the high level make it clear that guidance documents are very valuable, that we support the development of new guidances. We recognize that guidance drafting is resource intensive. It's very easy for people like us to stand up here and suggest 43 additional things that CDRH should be doing because we're not the ones that have to do a lot of the work. And so we've recognized that and tried to be strategic in some of our thoughts that we will get into.

I think it is also critical to point out that drafting is absolutely critical here. Stakeholders must read guidance documents with a high level of precision and literality, if that's even a word, because these are the

documents that guide and control what we do. And so, a lot of the comments, a lot of the processes are to ensure that the words accurately, completely, and fully describe the purpose and the intent.

Improving the guidance system is all of our responsibilities, not just the Agency's. And the comments we have here are also intended to look at the process, not just from guidance development, but frankly from the total product lifecycle approach, which gets into not just what happens to get the guidance released, then what happens through the entire lifecycle of the document. And therefore we start with the pre-draft process. Some of the ideas have been discussed before. I will not repeat them. And some of these we're going to base on information we just learned today.

The first key point here that's been mentioned is increase stakeholder input as the draft is being developed. And ideas here include having stakeholders provide a two- or three-page overview of key issues or key concerns. And when you think about a lot of the work the Agency's already done, you can see some linkages here. For example, the Guidance Initiation Form -- I think I got that term right -- sets forth the need or the purpose of the guidance. If that could become public and say, okay, folks, give us two or three pages. Here's where we think the issue or problem is. What should we be thinking about? What are the big pitfalls?

And I know the modifications guidance is kind of the constant example people use. I think at the end of the day it's an example of a process

that after some pain actually worked. And you can imagine a system in which the Guidance Initiation Form said here's what we see the issue is, and the input beforehand may have prevented a lot of the misunderstanding that occurred throughout it. We've talked about workshops, et cetera.

The other challenge in the creation is just process transparency. Where is it in the process? What stage are we at? And whether this links into the guidance tracking system that already exists or something else, it's very nice and very important for stakeholders to know, is this at HHS, is this at the Commissioner's Office, is this at OMB, so we know where things are, so we understand the process.

As part of that, I think it would be very beneficial to have a better understanding for the criteria by which guidances get kicked to HHS or over to OMB. It, frankly, to many of us is a black box. It's going to OMB because it needs to go to OMB. Well, why? What are the criteria? And that's important for people in planning and in also providing input. So, a process by which all stakeholders understand where in the development process things are we think would be beneficial.

The next two comments actually come together, and this is new guidances, what should be developed, and there are actually two aspects of this. One is, is there a need for the new guidance? Secondly, what should be the priority? Those are related but different questions.

So, the first comments here -- and a lot of this has been

discussed, so I'm not going to repeat it -- is input into need. Annual regulatory forums. I think a meeting of this type every year could be highly valuable for getting very specific and very nuanced input. A process for stakeholder identification of needs -- and we'll get into this in more detail in a minute. But identification of what we call "aging" documents. What's become obsolete for any one of a number of reasons? So, this is development of the need part of the equation.

The next is then the prioritization part. Yes, there may be a need for 10, but which are the 3 most important? Part of that are discussions such as this. Part of this also I think is a defined process for submitting proposed guidance topics, and also substance. It is possible for people to prepare proposed guidances for the Agency. That's a process, which is not well understood by the vast majority of us, and may be a process, which could help the Agency, if there was better understanding of how that process can and should work, when it's beneficial, how it's beneficial, et cetera.

Define criteria for determining the appropriateness of a new guidance, its urgency. And, again, this may link back to the Guidance Initiation Form, which does have, as I understand it, some urgency information. If we can link the public input into that type of documentation, we, I believe, can improve the determination of priority or urgency of a document.

There is a problem of the perpetual draft status. I often joke

with my class there's nothing more permanent that a draft guidance. And that's a bit of an exaggeration, but sometimes it's there. And it's a tough problem. We recognize that up front. And one option, which I think has a lot of problems with it, but people have at least talked about it, is after a defined time period the guidance is withdrawn, the draft guidance. Well, that means you've got to start the process over again.

The other option is that after a preset time period, 30 months -- we're just throwing this out for discussion purposes -- there's a comment period that's reopened. Thirty months, you're getting close to the 1,000-day time frame. If something is taking that long, from our perspective, there's a reason for that. What's the hang-up? What's the difficulty? Why isn't this going through? And a reopened comment period would both be an incentive to get things done, but also then an opportunity, if there is a defined, known issue with that draft, why it's not going through, why the Commissioner's Office has a challenge with it, or why the Center Director has a concern.

It allows all stakeholders to understand and address that, to assist in the process of breaking through whatever that challenge might be. And, again, this is based upon the view that there is a reason why it hasn't gone through the process to finalization in a faster time frame.

Now, if guidance documents are taking, you know, five years to get finalized, and there isn't a substantive process or problem with it, maybe

it wasn't that important a guidance. So, if we understand the reasons why it's taking time for a guidance to be finalized, that can link back in this close-loop system into development of criteria for the creation of new guidance documents. So, again, you see one of our things, one of our concepts here is this total product lifecycle, the feedback loops that allow us to learn while we're going through the process.

The challenge of keeping guidance current. There are a number of challenges here. There can be changes in technology, there can be changes in regulation, there can be new policy issues that arise, or whatever happens to be. But, again, we think that it's important to view guidance documents through a total product lifecycle. So, there are a couple of thoughts here for consideration, one of which the Agency has talked about, which is a streamlined process for what I will inartfully call the administrative and consistency updates.

There are new citations. You know, there's a new standard that's been already adopted by the Agency. Just keeping things fresh, keeping things current. But also then you can have a periodic. Pick your time frame -- there's no magic to a time frame, 5 years, 8 years, 3 years, 10 years, whatever -- for a reassessment of each guidance. Is it still current? Is it still needed? Is there a problem with the guidance where, you know, Section 3 no longer works, the rest is still fine? And it's identification of those.

Now, one of the initial reactions here, justifiable, is if the

Agency spends time doing this, they're not going to have time on other activities. And this is an area where I think all stakeholders may be able to benefit and help the Agency. So, for example, if you opened a process by which let's say 10 years, okay, any stakeholder that thinks there's a problem or the guidance is obsolete, tell us. So, get the stakeholders to do a lot of the work for the Agency in identifying whether there is a need for the guidance to be modified, updated, obsoleted, whatever is the most appropriate approach. During this reassessment process, again, absent special circumstances, safety issues, whatever, the guidance remains in place. So, this is an area where I think the Agency may be able to offload some time and some work.

The next challenge is the use or the inappropriate use of draft guidances. All of us have experience with stakeholders/Agency using draft guidances as final. These are drafts, and it's critical to remember that. Some ideas here: To separate draft guidances from final guidances on the website. Right now they're all together, and it's very easy for people in going through that just to see this laundry list. Some simple things: Mark every page with "draft." We all see the documents that have the big, you know, "draft" on each page.

Prohibit the use of draft guidances in regulatory decisions, inspections, enforcement decisions, et cetera, et cetera, so we don't get into this habit of using draft guidances as final. And this has to apply to all of us. Training of Center and the field force that a draft guidance is simply draft, and

what is the appropriate and what are the non-appropriate uses of that. And if there is a challenge or a concern that somebody is using a draft guidance inappropriately, a prompt escalation process for that.

Usability. Guidances are of value only if people can find them and use them. And so, how do we increase the usability of guidances? I think everybody gets to stand up here and beat on the website and how it's impossible to find a guidance and how many of us don't even bother with the FDA website. We go to Google and see if we can find it there, including some of my friends in the Agency that do that as well. But it's searchability. And, look, the technology tools exist, and we all know that.

Other concepts. Ensure that we have one topic. Maybe it's a broad topic, but one topic per guidance, so if I'm looking for X, I know where it is. Clear descriptive titles. The other is to avoid the surprise off-topic statement. I'm reading a guidance about Topic A, and all of a sudden there's a zinger about something that's not the topic du jour. So, ensuring that we have a defined scope of the guidance and that we stay within that scope.

We encourage the Agency to increase the use of guidance as citations or support in regulatory decisions: deficiency letters, 483s, whatever it happens to be. And, again, we're talking final guidances here. That, I think really helps all stakeholders understand the Agency's thinking, understand how guidances are being used, and to keep everybody essentially within the scope, the intent of that guidance and that guidance process. This obviously

requires ongoing education, Center, field force, stakeholders, et cetera, again so all of us have a role in ensuring that this process works.

The applicability of external standards and frameworks, something that's been touched upon, how we can streamline the process of appropriately incorporating consensus standards into the U.S. system, if they comply with U.S. law, U.S. policy. Obviously that's the requirement here. But, again, is this a way that we can streamline the process?

Related to this is an area where I think the Agency can help, and that's to increase the communication to stakeholders -- these external non-FDA framework or standard development activities. Often when I'm speaking -- not to this group -- but I ask a simple quiz. How many people have heard of IMDRF? I'm giving a talk tomorrow to the Minnesota State Bar Association. I will ask that question. If history is an example, 10% or less of the audience will have heard of IMDRF.

And so, if we have better participation in -- I'm just picking on that because it's current right now with a couple of regulatory frameworks -- if the Agency could inform people that there are these externals, IMDRF, standard setting groups, whatever it is, they are working on this subject, get involved in at that point in time, then when that output comes back to the Agency, it will better reflect the thinking and the concerns of all stakeholders closer to final. So, think about ways in which we can link, and just inform U.S. stakeholders of these non-FDA initiatives.

Now, I'm going to go through this list. These are simply examples of possible guidance priorities to be considered. You can add others to these, such as the contrast guidance that's been hanging out there for a while. We'll work with the Agency and get this to them in a bit more detail. But providing the Agency with this type of information with prioritization I think is the obligation of all of us so that the Agency has that input as they try to set their priorities. And, again, these are just samples of ones that are currently important.

So, how do we conclude this? Obviously, everybody is here because the guidance process is important. And the process needs to be maximized to ensure high quality and current guidances. We need to remember that draft guidances are just that. They are draft. We also -- and I'm talking to all of us -- need to remember that guidances are just that. They are guidance. These are non-binding. Different special circumstances may mandate or benefit from somewhat different approaches.

So, we have to make sure that draft guidances are used appropriately and final guidances are used appropriately. And, finally, all of us are responsible for this system, and all of us need to ensure that we are value added participants, that we're knowledgeable and we stay engaged. And, finally, I appreciate the Agency's openness and the data they supplied, and their willingness to think through this important issue. Thank you.

MS. STADE: So, thanks so much Ralph, and also Janet. I really

appreciate those different perspectives from industry. And I think we'll have a lot to discuss during the two panels this afternoon.

We so have one more stakeholder perspective, Paul Brown, Government Relations Manager at the National Research Center for Women and Families, Cancer Prevention and Treatment Fund.

And after this, we'll have a question and answer session.

MR. BROWN: Thank you very much.

Good morning. It's good to be here. I'm glad to be a part of the stakeholders. Just a quick thing about myself before going too far, I frown a lot. That doesn't mean I'm angry. That's just my default position.

(Laughter.)

MR. BROWN: So, my wife told me I should smile more often. And then we went to a reception, and she said stop it. I said --

(Laughter.)

MR. BROWN: I said, why? She said you look like a funeral director. So, I'm not angry. It's just my default position.

It's interesting to me that often we have different perspectives in industry, and we do have some different perspectives on this. But nothing that was said by Ralph or Janet this morning do I really disagree with at all. I think that we're pretty much on the same page. Maybe not in the same paragraph or the same sentence, but we're pretty close. So, that was interesting to me.

We just changed our name, so I want to plug that. We are now the National Center for Health Research, and that's our mission statement. We do not accept funding from the medical device or pharmaceutical industry -- a disclosure just like Ralph was doing -- so we don't have conflicts of interest.

As I just mentioned, when I was going through this, our perspective as patients and consumers is actually -- on the guidance development process is very close to industry's. We want clear, concise, understandable draft guidance documents with precise terms, as Ralph and Janet both mentioned. You know, we get into the process, I think it was at about Phase 7 in the past. When Ruth was talking earlier, that's when the draft guidances come out, and that's pretty late in the process. But I do have some suggestions even at that stage for what we would like to see.

We'd like to see a summary of the guidance document almost like what you're talking about on GIF, right up front. You know, we want to know why -- is that an issue that patient and consumer groups can quickly determine is this a priority for us? Do we need to comment on this? And that would be quite helpful.

Often I read quite a bit of those draft guidances, not all of them, but quite a few of them, and it takes me sometimes several pages before I get to the gist of what they're getting at. I mean they'll state the purpose usually right up front, but the specifics of it I think you could really

do in a thumbnail right up front, and it would really save, at least our organization, a lot of time. I mean you were talking earlier about resource poor. Most of the nonprofits that I've been affiliated with are always struggling with resources. We don't have a lot of staff, so that would be very, very helpful for us.

Some of the things that a summary could include: the purpose of the guidance, what's the issue, what's the problem, how the guidance document will affect the data requirements of the FDA's review for safety and effectiveness -- we're always focused on safety and effectiveness. That's our main thing, and when we see these new guidance documents, especially the ones that have special controls, that's what we were focusing on.

We also want to know who requested the draft guidance. Was it the FDA, was it industry, was it a patient and consumer advocate? Was it required by statutory deadline? Was it introduced to save FDA and industry resources? And we want to know, as specifically as possible, which medical devices are covered by the guidance document. That may seem very, very obvious, but sometimes we spend a little of time trying to figure out exactly which device that is.

And the summary guidance continued, you know, the guidance should be -- one of the things that we're worried about or concerned about is the enforcement mechanism. As Ralph mentioned, these are not binding, and so we're always concerned that if the special controls around -- regarding

safety, what if they're not met? What are the enforcement mechanisms?

We're in agreement with the FDA's working group recommendations. You know, streamline the development of the guidance, reduce the time between issuing the draft and the final guidance, make it easier to find the guidance on FDA's website. I guess I'm pretty much alone in this. I can find them fairly quickly on the FDA's website. And I think that the new guidances that they've issued where they have their most recently released guidances, that's a really nice quick way to get to the new guidances. Now, if you're going for the older ones, it may be a little more of a challenge, but I find it fairly easy right now. I think they have improved that, so I think that is -- a little applause for that.

The guidance documents I think really are focused on industry, and they should be. I mean these are the -- you know, these are the things that really affect industry's livelihood and their bottom line. However, patients and consumers and public health organizations, you know, we're concerned about the safety factor because people's lives depend on these being safe and effective. And we'd like to get involved, as resources permit for us to, as early in the process as possible. And I'll touch on that in a minute or two.

As I've been saying, our interests overlap with industry's, but we do have a public safety element in that. And we're very concerned on the safety and effectiveness that when they're doing these guidances, we want to

know about the labeling and promotion, how the FDA plans to prevent off-label promotion. We want to know about testing the products. What will FDA do if the guidance is not followed? Those type of issues.

We are concerned that the guidance documents seem to be focused more on expedited clearance and approvals than on safety and effectiveness. Some quick examples from some of the guidance documents I've just pulled up randomly: speed device development; enable faster development of medical devices; expedite the development, assessment, and review.

I don't know what the rest of you did when you went through college, but I drove a tow truck. And it was a pretty good job actually. I helped out a lot of people. But sometimes we had to go to a wreck, and almost all the time the wrecks were caused, if they weren't from DUIs, it was from excess speed. Speed is good, but it also can be dangerous. We want to make sure that the safety and effectiveness issues, especially safety issues, are covered.

Basically, patients and consumers, they want not necessarily quick access to new devices, but they want access to devices that are proven safe and effective. And our focus really as patient, consumer, and public health organization is on the part of FDA's key mission of protecting the public health.

As Ralph mentioned, and probably some other folks too,

guidance documents are not legally binding. Our problem with that is, again, how do you enforce them then on certain things? How important are the documents? Well, I think that they're not always a top priority. I think like if -- my apologies to Ruth Fischer, who they're a priority in your life, but I think just reading the materials, if the subject matter expert is getting behind on something else, they get pulled from that guidance and they get put on something else, so that the priority is not always there.

Are there too many guidances being issued? I believe the number is 46, now 47. We think so. I mean our organization, we just don't have the resources to review that many documents, that many guidances. And that's why to us a summary statement for the guidances is extremely important.

The working group noted that some guidances that are approved for development are never completed. I think that's a problem. I think it's a waste of a lot of resources. I think the guidance should be prioritized, as Janet and Ralph had both mentioned too, but I think our focus again is prioritizing the ones with significant public health issues.

Brief comments on outreach. I know we're going to discuss this a little bit later. *Federal Register* Notices I don't think are the best way to inform independent patient and consumer nonprofit groups. I do read them religiously, and they are the worst thing in the world as far as on a literature level. But I do like the FDA's *Federal Register* Notices because they do have a

summary at the front that is quite helpful. And not all the agencies do that.

I would suggest that the Agency, CDRH and FDA, starts being a little more proactive, and anyone that comes to one of these meetings, anyone that goes to a webinar, immediately get their email addresses and send them the Daily Digest Bulletin. You're doing a pretty good job on that. It's much easier to read and comprehend the information on the Daily Digest Bulletin. But I'd even go further than that. I'd actually make like weekly digest bulletin. We're all just inundated with emails every day, but if you could make it like a weekly thing, that would be quite helpful.

Conclusion. Consumer, patient, and public health advocates want many of the same things that industry wants: clear, concise guidances. We want a summary that includes the key information. We want clear, specific guidance relevant to safety and effectiveness, again, labeling, testing, and enforcement policies. We want the FDA to make it easier for patient and consumer and public health advocates to be involved. And, again, I would emphasize sending us the emails and maybe the daily or weekly digest. Thank you for your time.

MS. STADE: Thank you.

And if you're able to stay a little later afterwards to show me how to use our website, I'd appreciate that.

(Laughter.)

MS. STADE: So, I must say I'm actually very gratified that there

was a fair amount of overlap in the different presentations. I think that's helpful to us as we think about what we've heard today and, you know, what we can do going forward to continue to improve our process.

We are entering our question and answer phase. And I guess what I'd like to ask folks to do, if you have a question, come up to the microphone, helpfully situated in the center of the audience there, and you can ask me questions. If I don't know, I might pull up some of my questions. You can say if your question is for one of our other presenters, and then I'll ask them to come up either to this microphone, or to any of these microphones, and respond. Hi, there.

MS. STEEL: Hi. Good afternoon. My name is Danielle Steel (ph.), and I actually appreciate this opportunity. And I'm going to use it to provide a comment as opposed to really posing a question. It is including a request though.

So, I'm providing this comment on behalf of the Combination Products Coalition. Over two years ago the CPC filed a nearly 400-page citizens petition. And in that petition we request fundamental changes. Many of us have stated them today, and some of them have been noted as priorities. And those fundamental changes are to the good guidance practices. Our petition was another step in a nearly decade-long effort for the CPC to improve the guidance development process. Although the length of our petition was partially driven by the complexity of the issue, it's also

driven by our desire to chronicle our repeated requests to improve this process.

The key improvements we have been requesting for -- about since 2004, include: first, adopting procedures designed to ensure that the content of the guidance addresses the public's key concerns by making it easier for the public to propose guidance in a manner that ensures it is responded to by requiring the Agency to respond to comments submitted during the development of the guidance and by embracing informal communication with the public before and during the development process; second, ensuring the timely development, finalization, and withdrawal of guidance documents by establishing metrics and tracking compliance with such metrics; and, third, refraining from using podium guidance or warning letters or other communications to announce new policies, specifically. Hence, that should be set forth in guidance documents.

In the two years since we originally filed our petition, we have filed comments to our own petition offering additional suggestions on how to make these key improvements. In those two years, we have not received a formal response from FDA, and the CPC asks that FDA move as quickly as possible to respond to that petition.

These issues are important, and with every day that passes, industry continues to struggle to understand what is expected in terms of compliance, and what pathways exist for new product regulatory approval

and clearance.

We look forward to continued dialogue with FDA. And, again, I appreciate your time and consideration and all that's being shared today.

MS. STADE: Thank you very much and appreciate that was a comment rather than a question. I'll just make a few observations that some of the comments contained in that petition do overlap with what we're hearing today and appreciate that these are areas that we really do have to go back and take a hard look at.

I'll also just comment, some of the other matters commented -- raised in that petition bring to the fore this whole question guidance versus rulemaking and, you know, which one do we use and what point do we so burden the guidance process with procedures that it's really not very different from rulemaking? And I'll just throw that out there. I'm sure there's going to be additional discussion of that, but that is something we struggle with.

Anyone else? More questions, comments? Please -- in the, I don't know, fourth or fifth row.

MS. GUPTA: Elora Gupta from Otsuka Pharmaceuticals. I had a question about drug device combination products where you have oversight by both CDER and CDRH, and therefore, guidances from both CDER and CDRH are applicable. And the final approving Center though is CDER, whereas we often struggle with where we are following, to the best of our ability and

understanding, CDRH guidances. Then we are not clear to the extent in which CDER is following those guidances or interacting with CDRH in that same manner in the interpretation of the guidances.

So, could you please comment on that? And how much of that do you take into consideration when you develop your CDRH-specific guidances? Thank you.

MS. STADE: Sure. So, that's, you know, a whole -- we've spoken about the complexities in the guidance development process. And if you're talking about a combination product, it is -- I don't know if I'd say you double the complexity, but something thereabouts. But we do -- if we're developing a guidance document on a product that's -- on a combination product, we would have CDER input and CDER clearance of the document. So, the document should represent the thinking of both Centers for a product that is a combination product.

MS. VEOUKAS: Hi. My name is April Veoukas from Abbott, and I have a couple comments. One, I did want to just echo the comments made earlier about clarity on draft guidance documents and that they are a draft and not to be followed. I think that getting additional clarity in there would really be beneficial to the process overall.

And then I know with some of the guidance documents there are phone calls that have been set up announcing the introduction of the document. And I believe that maybe to have more dialogue and more

questioning, maybe having those phone calls after the document has been available for about a month would better facilitate questions and, you know, give people an opportunity to take a look through the documents and really formulate their questions.

And then this is I guess an observation in the sprit of open dialogue. I hope this comment's not out of line, but it seemed with the process, the internal process that there are guidance documents where there is initial drafting, but then later they're revised substantially after a hierarchical review. And then maybe having those discussions earlier in the process, you know, would elucidate those issues that would be -- would necessitate rewriting the document so that if there are different perspectives at a higher level within the Agency, then getting those out earlier in the process would reduce the time to issuing those documents.

MS. STADE: Thank you. That is something we actually struggle with internally. You know, when it makes sense to have everyone at the table at the initiation process so you can air these issues up front and one hopes address them at the outset, versus when it makes sense to have things go through the regular review process. And there are a couple of considerations that go into that. You know, one is again resources and whether folks, you know, higher in an organization have an opportunity to really sit down at the outset.

But then also, you know, you find guidance documents have a

life of their own. And you may think that you fleshed out all the issues when you sit down initially. And then, as you're developing, just new issues arise and even -- and then sometimes it really isn't until you've read it. And I think this is a little bit -- this goes to a little bit what we've heard in some of the stakeholder presentations about the need for precision in the language. So, you think you've raised an issue and come to agreement on an issue, and it's not till you see it written that you realize you're coming at it from entirely different perspectives.

So, I think the suggestion is a very good one. I also think implementing it -- it's probably a best practice to do things that way. It doesn't always turn out the way you intended. That's just an observation.

More questions and comments? And not just for me, folks. We had all sorts of very -- I thought every engaging and informative presentations, so questions for me or for others are welcome. Hi.

MS. CAPARILO: Hi. My name is Emily Caparilo (ph.), and I support a few programs at DARPA who are all really interested in the development of novel technologies and usually novel approaches to devices and other technologies. And one issue that we repeatedly face is that even when we're able to establish a highly successful proof of principle, our performers in industry and otherwise are hesitant to further develop these products, often because there might not be existing guidelines or guidance on how exactly to move forward in developing these devices, and it becomes

very risky for them.

So, my question is really how the guidance process can help in this situation? I was particularly interested in the leapfrog guidance that you mentioned, and my interest is -- or my question is really how do -- what kind of initiative or momentum do you need to establish leapfrog guidance? Would that be appropriate in this situation? And if so, how would you weigh the priorities of developing proactive guidance for novel things that might be coming down the pipeline against some of the urgencies and other factors you talked about?

MS. STADE: Right. And I think that would -- you know, the prioritization piece would reflect the health need that the technology is intended to address. But then, even after you prioritize something, well, it's one thing to have it prioritized, and then just -- it's the level of difficulty in actually developing that. And so -- and Leslie spoke, and I think a few other people spoke about, you know, is there any way to have something that's not really guidance, but that can facilitate the development of guidance, some sub-guidance creature?

And I'm thinking of something -- you know, and I hope I don't get into trouble for even breathing the word -- like a discussion draft, something like that where it really doesn't represent the thinking of the Agency, but it's something folks can react to. Is that something that would be helpful, for example, if you're talking about a technology that FDA may not

have seen before that's even novel to folks who are developing it? Is it useful to have something like that?

Because we do find that people -- the quality of the responses we get to something that's in writing are -- tend to be higher than the quality when we just say, hey, what do you think? So, is that one mechanism? And then, you know, again, that speaks to how we get something on the table, and then whether it's prioritized. But then the level of difficulty is, you know, the level of difficulty. How foreign is the technology to us? And, you know, can we leverage the expertise to develop that document? But it is something that we are thinking about in a few different areas.

MS. TRUNZO: I think the previous commenter brought up something, which is something that is challenging to the industry with new technology. And so, from our perspective, you know, it's often the case where the reviewer hasn't seen the technology before. And so the requirements often become, you know, tremendously burdensome because the reviewer hasn't seen it. And there's this tendency to try to ask for everything you could possibly ask for because you haven't seen it. And I think there is a challenge with that.

And I don't know whether it's a discussion draft or whatever it is, but there's got to be a mechanism by which, you know, FDA can consult with experts to ensure that, you know, the data requirements are not excessive in these cases for breakthroughs to encourage the development. I

mean that's -- we've been talking about that for some time.

MS. STADE: Thank you. Yeah, and so the -- you know, and those are some cases. And particularly if you're talking about really a brand new technology where it might make a lot of sense to do some type of public forum before there's even a draft guidance out there, so we have the discussion. And that's the type of forum where something like -- you know, something that doesn't represent our current thinking, but that represents a possible approach could be very useful, again, to spur conversation and to get the input we need from experts. Thank you.

DR. BINION: Hi, Nancy. Steve Binion with BD. I was just wondering if you could comment on, well, any aspect, but, you know, sort of the evolution of a process that I think we've seen more and more recently, which is FDA websites providing I'd say very quick and responsive interaction mechanisms for, you know, sponsors, others with questions, you know, the mobile health website, for example, UDI? And publication, you know, of those responses or making them available back to the -- from the Agency on topics that are of much potentially broader public interest, but, you know, others who are interested might not be aware of that, you know, those particular interactions, et cetera. And also, is this sort of an evolution of guidance practice and thinking within the Agency?

MS. STADE: So, I'm glad you asked that question, and particularly concerning UDI. This is an area where we're struggling frankly

and where the interest and the desire and the legal requirement that we follow, GGPs, is -- it's creating some challenges. And we're trying to do something above -- everything above board. At the same time we're hearing very strongly from our constituencies, they want to know how they can comply. And we have been able to give very case-by-case, case-specific responses to questions. That's different from guidance.

So, if somebody asks us -- you know, describes very particularly what their particular product is, and how the requirements that are in the rule are going to apply, we may be able to answer that. But what we can't do, without using the guidance process, is develop policy. And so I can tell you, you know, this is an area where we're doing our level best to get the guidance out as quickly as possible so we can do it in a way that's appropriate and nobody can say we're trying to circumvent GGPs. But I'll just be very blunt. It's been incredibly challenging.

And the way we do it is we can -- if we have a very specific question, we can answer a specific question. We can answer a specific question on a specific set of facts. What we can't do is develop policy. We can share the specific question, but is there a risk with that that the specific question will be applied beyond the specific set of facts and folks will not only accuse us of developing policy, but perhaps apply the answer in a way that's not -- that wasn't intended?

It's a challenge. That's the most I can say. We're trying to, in

that area, particularly with UDI, to balance the need for very timely responses to questions with our obligations to follow GGPs.

Additional questions? Thoughts? Comments? Criticisms? Praise? I'm struggling.

Okay. Well, this afternoon we will reconvene an hour from now. We'll reconvene at 12:45, and we're going to start off then with our first panel. That's going to be on best practices. It's going to be a bunch of us from FDA and CDRH, and also several of our stakeholders. I'm really looking forward to having a good conversation. So, enjoy your lunch, and I'll see you back here at 12:45.

(Whereupon, at 11:46 a.m., a lunch recess was taken.)

A F T E R N O O N S E S S I O N

(12:50 p.m.)

MS. STADE: I just realized we said we were reconvening at 12:45, and I think we're past that hour, so let's get started.

The first thing is, somebody lost a set of keys. And it's believed that they belong to someone participating in this workshop. So, you might just check your belongings. If you do find that your keys are missing, they're in Building 1, or at least one set of keys is in Building 1. I can't tell you whether they're yours, but somebody has found a set of keys. So, please have a look.

There were a few written questions also submitted on index cards that we weren't able to get to at the first question and answer session, but we will be getting to those at the second question and answer session after our two panels this afternoon, so don't despair. We will be responding to your questions in addition to questions from the webcast.

So, for this part of the workshop, we're going to have panels, and I actually am going to ask folks, if you're on the panel, to come up and take the seat beside your name tent. And how this is going to work is I do have a series of questions that I'd like to ask, but I also have -- after having heard the excellent presentations this morning, I have some questions about what we heard there. And these are really intended to be -- to continue the constructive conversation we began this morning.

So, I will be asking about some of the things we heard, and I will be presenting questions to individuals on the panel, but also, if you're on the panel and you'd really like to contribute something, please just do raise your hand or somehow signal to me that you'd like for me to call on you, and I will do that.

All righty then. I'm going to take my seat with the other panelists, and I'm just going to ask that each member of the panel introduce himself or herself. Give your name and your affiliation, and then we'll get started. Phil.

MR. DESJARDINS: Phil Desjardins, Associate Director for Policy within CDRH.

MR. McFARLAND: Scott McFarland. I'm a policy advisor in CDRH's Office of In Vitro Diagnostics and Radiological Health, or OIR.

MS. ROSECRANS: Heather Rosecrans with the Medical Device Manufacturers Association.

MS. TRUNZO: Janet Trunzo with AdvaMed.

MS. STADE: Nancy Stade. You know me by now.

MR. BROWN: Paul Brown. I'm with the National Center for Health Research.

MR. HALL: Ralph Hall, Faegre Baker Daniels and the University of Minnesota Law School.

MR. BEINKE: Hans Beinke. I'm with Siemens Healthcare and

representing MITA. I'm also with the Coalition and with AdvaMed.

DR. BRINDIS: Ralph Brindis, clinical professor and cardiologist at UCSF and involved in the registry for the NCDR and representing the American College of Cardiology.

MS. KRUEGER: Angela Krueger. I'm the Acting Associate Director for Guidance and Regulation in CDRH's Office of Device Evaluation.

MS. KUX: Leslie Kux in the Office of Policy at the Office of the Commissioner.

MS. PIRT: We have a request that people talk directly into the microphone?

MS. STADE: Okay. And also folks just if you're like me, not the most technology savvy, it looks like you hit the red button, and that'll help.

So, I did prepare a number of questions for this conversation, but we had such a good discussion this morning and so many good suggestions that I actually wanted to begin by having a little bit more of a conversation of some of the suggestions we heard from our stakeholders. And what this is intended to do, I'm going to begin at least by speaking to some of the folks from FDA who are involved in the guidance process and get some responses to some of those suggestions.

And you might hear that's a great suggestion. You might hear, well, these are some of the challenges with this suggestion. We're not in any way taking a vote on whether this suggestion is one that we should move

forward with. We're just trying to provide some greater transparency on what might be the challenges, the pitfalls, and also the benefits of adopting some of these suggestions that we heard this morning.

And so I'm going to be with, Leslie, if you don't mind, talking a little bit about the suggestion we heard for either participating in ongoing workgroups or having greater involvement actually during the development of a guidance document. And what do you -- I think it's easy to see what some of the benefits could be of that in that, you know, that way when you put out a draft guidance document, the response should be something you can predict. And also you might be able to issue a draft that's going to be closer to the ultimate final guidance.

So, there are a lot of benefits in efficiency and in actually getting it right when we announced draft current thinking as opposed to when we get to the final. But I think it would also be beneficial to talk about whether there are any challenges for FDA to do that. And if you have thoughts about how those could be addressed too, that would be very helpful.

MS. KUX: Sure. I think existing workgroups or third party groups I think often have a lot of useful input to give, especially if they're focused particularly on that specific issue, which -- and oftentimes there are various workgroups set up to deal with some of the issues that we're looking at. I think a couple of the challenges we face are around transparency, as

we've talked about the concern that we have to make sure that all stakeholders have, you know, equal access. Or, I suppose, maybe you all look at it as, you know, equal lack of access.

But that we're equally available to all stakeholders and that -- and also that stakeholders are aware of what everybody is saying. So, for example, if we do have meetings with individual stakeholders, we'll put memos in the docket so that it's -- people know that we've met with stakeholders and everybody's comments are in the docket. So, part of it is to make sure that there's a full -- you know, one constraint is to make sure that there's a full sharing of all of the information that we get.

I think perhaps the other challenge relates to the Federal Advisory Committee Act, or FACA, because it -- which puts a lot of constraints and structure and was intended to put constraints and structure around the Agency's use of outside advisory bodies. And so we need to -- so going to an existing group can create real issues in that regard as well because it looks like we're using the group as an advisory committee.

I think, you know, that's the reason those are -- those constraints are the reasons why you see us holding a lot of workshops for the non-FDA folks in the room because that's an opportunity for everybody to come together and present their perspective to the Agency and to each other.

MS. STADE: And so I'd just be interested in hearing -- we have

on our panel several folks primarily representing industry. We also have a few folks who represent other stakeholders: Ralph Brindis and Paul Brown. And I wonder if either of you or both of you would have any comments about that. And I'm turning to you because often we hear interest from our industry stakeholders who are commonly the individuals most directly and immediately affected by our guidance documents, although they of course do have broader impacts. But that's often where we hear an interest in creating these stakeholder groups.

And, first, whether you have concerns when those groups are formed and whether you think there are ways to include groups other than industry when those conversations take place, or ways to just create greater transparency.

DR. BRINDIS: Okay. I'm guessing you're going to go -- I'll go with this, Ralph. Ralph and I -- it's an uncommon name, and so every time I hear Ralph being called, I'm looking over at myself, and I'm sure you're doing the same thing.

First of all, I want to acknowledge Nancy and the FDA for the effort that you're having today. And also all my dealings with the FDA in terms of a true desire to always get better, and it's been an incredible pleasure in all my dealings in working with the FDA and what you're trying to always accomplish.

So, I want to comment on Leslie's issues here about how do you

maintain transparency and move things upstream. And I think that was sort of a common theme that I heard today, beautifully articulated by Ralph Hall. I actually think if the common goal here is to have a document that everybody is happy with, that the end result is exactly -- that meets the needs of everyone, that it accomplishes the goal and at the same time has a -- from initiation to completion is as short as possible. I actually do believe that the further upstream stakeholders can be involved may make the end product not only a better product and at a quicker time, although I appreciate the issue that you raised. How do you ensure that it's not a one-on-one conversation and that you have an open dialogue?

You don't mind me keep on going a little bit. So, one of the ways that -- I hope.

(Laughter.)

DR. BRINDIS: I won't go back up to the podium. But one of the ways one could imagine doing that is that at present -- and I don't know if there's some federal statute that you have a 90-day comment at the final release of a document. One could imagine, particularly hearing that all the comments come back in the last week, is that I think that the communities probably have been Pavlovian responding to this 90-day thing. And my intuitive guess is that you could shorten that, you know, maybe to 60 days knowing that other areas of the government have a 30-day window for some of their things.

At the same time, at the front end have a very short period where a concept of a document is put out in a broad outline form. This is what we want to take on. These are sort of the areas in that document that we're thinking of potentially covering. Do you think we're on the right track? Do you have some idea as to where we should be going in this document? So, I could imagine the amount of lead time, that small lead time open stakeholder involvement could really streamline a lot of the work that's done behind the scenes that you go through, your Phase 1's and your Phase 2's, prior to the open comment.

So, thanks, Nancy, for that opportunity.

MS. STADE: Thank you, Ralph Brindis.

(Laughter.)

MS. STADE: Hans.

MR. BEINKE: Yeah, Hans Beinke with Siemens Healthcare, and I don't think I've ever been at a meeting where I had a Ralph on my left and a Ralph on my right, so --

(Laughter.)

MS. STADE: We didn't plan that.

MR. BEINKE: I guess the question that I would have this whole business of making sure that you're fair and objective in terms of stakeholder input, I mean you do have those meetings right now where you sit down with different groups. And I don't think you're meeting with every single group. I

mean how is it that you support that rationale now?

MS. KUX: We'll meet with individuals, but what we don't do is take a document to a group of people and say we'd like you to give us -- we collectively -- unless it's a formal advisory committee -- you know, we would like you collectively to give us your input on this document. But we do meet with trade associations, with individual companies. It's fine for us to sit with a group of people and hear each organization's perspective on a particular document. What I think is more problematic is to ask that group to sort of work as a body to help us with the document, for example.

MR. BEINKE: Yeah, I think it's safe to say that it's usually in the other direction where an organization comes to you, right? So, do you operate on the basis that if they --

MS. KUX: No.

MR. BEINKE: -- if they haven't asked?

MS. KUX: Pardon me, if they haven't asked?

MR. BEINKE: If they haven't asked, then you don't feel like they've been excluded?

MS. KUX: We do. No, I think we -- if we were going to -- if we thought a particular organization was interested in something and we wanted their input, we would let them know that we were interested. I think we do that regularly, reach out to people and ask and make sure that they're aware of things that are happening so that if they want to comment, they can. They

may have their reasons for not wanting to, but I think we do do outreach to make sure that all of our -- all, you know, stakeholders are aware of stuff.

There are some people that -- I mean we would expect that AdvaMed would generally be aware of what's going on, but if we were concerned that there was an organization that we thought would have an interest, then we would let them know. We wouldn't offer to meet with them, but we would let them know about the document.

MR. DESJARDINS: I think some areas where we've actually done that outreach is sort of when we feel like we're getting a single perspective. If we have three industry organizations that reach out to us and want to provide their individual perspective on something, and we feel like we're hearing one side of the story, we may do some prospective outreach to patient organizations or consumer organizations to hear that perspective directly as well.

MR. BEINKE: But what that says is that there's a judgment involved there, and it seems to make sense. It seems to work. I mean, again, I think in most of these processes, if an organization feels they're not being heard, they have every opportunity to raise their hand and ask for an audience, do they not?

MS. STADE: They certainly have the opportunity to ask. I would wonder -- and maybe I'll put to you, Paul, whether you think in some cases, you know, are there resource constraints or, you know, you also spoke

to the challenge of just keeping up with everything that's happening. And you raised one issue that I want to talk about later is the question of what's too much guidance? But just the experience of just being inundated by how much is going on and the need to prioritize what you're focused on, and while you're focusing over here, who knows what's going on over here? And I wonder if you could comment on that at all in light of this conversation?

MR. BROWN: Thank you. We actually would love to be involved as early as possible on these things because what we love to do and what we can actually are two different things. And I would like to thank the FDA for -- as Philip mentioned, they have reached out to patient consumer groups when the point of view has all just been industry. We've been contacted a few times that way. But, again, the ball's been moved along quite a ways before we're brought in. Ideally, we'd be able to actually participate earlier on. I'm not sure how that would really work out in reality.

I also want to touch on, just for a moment if I may, what Ralph said about the 90-day period. I think too that it can be shortened to 60 days, and with flexibility. So, if you have a request for additional time, then make it that way. I have no idea -- I'm sure industry works much differently than I do, but I have four folders on my desk with the months, and I print these out as soon they get there, and I look it over. And then I say, okay, can I put this one a month out? Can I put this one a month and a half out? And I have my folder going that way.

So, I don't actually work on them right when they come out. I don't know. Maybe I work a little bit differently than other folks. I'm sure I do. But I think that time can be shortened.

MR. DESJARDINS: I wanted to throw out a little bit of data on that. In terms of extending comment period, the Center has had -- depending on the nature of the guidance and some of the other issues that are surrounding it, we have gone out with 60- and 90-day comment period, respectively. We've also been very open to extending comment periods, if we get such request. I don't want to say we've done it 100% of the time, but in the last couple years, generally, when we get a request within the time frame asking for an extension with a justification, I think we've tried to accommodate those as much as possible.

MS. STADE: Janet?

MS. TRUNZO: I just wanted to comment on the opportunity to interact with stakeholders and when it's most valuable. And I gave an example in my presentation as an example of when FDA is seeking input on a device-specific guidance that it is developing. These are the cases where I think these interaction with -- for example, at AdvaMed we have a working group on heart valves, and we have all the heart valve manufacturers, or major heart valve manufacturers in the U.S. represented on that working group and giving feedback to FDA as it's developing the guidance document.

That's when it seems to be that it would be very -- it's very

efficient because as it is often the case, the real experts on any technical subject are often in the companies themselves. So, that was just one example of how there is an interaction that could yield a very quality document at the end of the day.

And as far as the 90-day comment period goes, I would say that we really prefer a 90-day comment period. I think in some of the cases when there's been a 60-day comment period, you've probably got a request from us, Phil, to extend it to 90 days. And it's usually because our consensus process within our organization takes that amount of time. If we have a working group that's already in existence on that particular topic, it's -- you know, that working group will be the main developer of the comments, but we just need the time from an organizational point of view.

MS. STADE: And let me just ask because the 90-day period has come up with several folks, does it make a difference what type of guidance document you're talking about? So, for example, of you have product specific versus something that cuts across all different products, all different devices?

MR. HALL: Yes.

MS. STADE: Would anyone like to elaborate?

MR. BROWN: Very nice. Nicely done.

MR. HALL: A couple of thoughts. Your broad cross program guidances require a lot more thought to understand the linkages, the interconnection, the implications, et cetera. And I think actually, Paul, you're

much more organized than I am. If you think through these, you start doing a lot of what ifs, and you start running examples through them, and that opens up a lot of avenues. And so, for some that are narrower, more specific, 60 days, 90 days is fine. I think there are a handful -- not all by any stretch -- probably well less than half that everybody recognizes up front are big-ticket issues that require a lot of thought.

So, for example, you know, the 510(k) program guidance. You know, that's really complicated and it's really important and people -- all stakeholders -- and I am a firm believer in inclusion -- all stakeholders need to understand what it means. And so I think the Agency can do some assessing of, you know, which of the big buckets it falls in pretty accurately.

MS. STADE: Okay. And, Ralph Brindis, you raised an issue when you responded to the first question that was also in the other Ralph's presentation, which was the idea of a high level summary of what's going to be in a draft guidance before the draft guidance is issued. And we spoke a little bit about the guidance initiation process and that we have something called the Guidance Initiation Form that discusses the problems, the urgency of the guidance, and is actually a vehicle for ensuring that the highest levels of Center management believe this guidance is something worth expending resources on.

And I think, Ralph Hall, what you suggested in your presentation was maybe it would be a good idea to share that with the

public. And I think that's a very -- you know, it's a very interesting proposal in that this is something we already do. And so I'd just like to talk with some of the folks who, like me, are very engaged in the guidance process, what they see as the benefits and potential pitfalls of that approach. And I'll just turn to Phil Desjardins to start that conversation.

MR. DESJARDINS: So, first, I just want to start off with I think there's a lot of merit in sort of the suggestion and the line of thinking that we're going down here. I think the idea of getting earlier input involvement has the potential to greatly improve the overall quality of both the drafts and the final documents that are coming out. But the issues I'm going to raise now aren't to shoot down those ideas, but to raise somewhat sort of the -- not necessarily the unintended consequences, but some of the other practical issues that we might be facing.

I think the first is oftentimes in that Guidance Initiation Form what's identified -- what is crystal clear is the problem that we're trying to solve. What often is more difficult to articulate, especially early on in the process before you've engaged internally at least, is what the solution is. And oftentimes those Guidance Initiation Forms early on lay out either a proposed framework or even a little bit more skeletal of here's where we're going but let's develop -- let's establish the work group, let's develop this policy, and let's flesh it out. But during that process we're also going to have regular feedback with managers within the Center and within the Agency to make

sure that we're on track.

I think one of the fears would be that if this became either a standard practice or a requirement is that it might stifle the identification of new guidance documents, and it might stifle our ability to solve some of the problems that we've identified. And that would be one of the issues that I would be concerned about is that if we tee up issues that are real issues and we're either too cautious or afraid of providing sort of even just sort of a direction that we're pointing either in anticipation of some negative reactions or that it might be taken out of our hands, I think that's one of the concerns the Center or the Agency might have with putting out some of those types of documents.

So, why don't we go one by one? Maybe I'll throw that out there, and if anybody wants to respond to that first concern?

MS. STADE: Okay. We'll start with Ralph Brindis and work around.

DR. BRINDIS: So, I totally acknowledge that. And so I guess my own personal vision although I'm -- you know, Ralph Hall spends more time in this area -- is not that the initial skeleton outline would have the solutions necessarily, but really focus on actually the scope and the direction. I sit on the task force for clinical practice guidelines for cardiovascular disease. And one of the worse things that we see is when we're asked to endorse or come late to the party to react on somebody else's clinical practice guidelines. Yes,

we have the opportunity to offer input, but it's not ours.

Wouldn't it be better since -- and I truly believe that the FDA thinks transparently and thinks about the stakeholders -- if you have things upstream, all of a sudden the stakeholders are involved proactively as more downstream reactively. And I think that's an honest and ideal goal to have.

MS. STADE: Hans, then Ralph Hall.

MR. BEINKE: So, I guess my question would be more to a little bit more on the process of the initiation form. I'm assuming that that has a life itself, and that you start out with something that goes through iterations, and then, you know, it's finalized. So, I'm not sure that I'm interested in your first iterations. I'm more interested in the last. And I think with what Ralph was saying is, you know, more interested in the scope and the objective of what the guidance is about.

MR. HALL: Let me agree with Ralph. You see a pattern here, I think. I think it's more important to know the issue or the topic and give stakeholders on all perspectives the opportunity in a streamlined fashion to set forth what I'll call, perhaps inartfully, the attributes of what a solution should contain and where the landmines are. And this can be done in parallel with all the other processes that you're going through so it doesn't slow things down.

And to build on both comments, if you get those attribute lists or the criteria for success, whatever you want to call it, early as you're going

through the development process, you'll at least have an awareness of what the primary issues are, or might be. And you can address them up front rather than I get them after the draft comes out when a year's work has already taken place. And you can also use that -- you know, and not for all guidances obviously. But if it's important enough, that then forms a basis for a public workshop, workgroup, whatever it happens to be, to further flesh out possible solutions, approaches, issues, et cetera.

MS. STADE: So, I'm going to turn to the folks who handle guidance processes in our offices, and that's Angie Krueger and Scott McFarland. And they really run the guidance processes out of the Office of Device Evaluation and the Office of In Vitro Diagnostics and Radiological programs. And those are the two biggest office-level guidance programs.

And I guess I'd just like to turn to you to consider, if we're talking about this process of, you know, getting input on some high level statement of what the guidance is going to be, what types of guidance documents -- if you think it would be helpful for certain types of guidance documents, when do you think that might be helpful and what you see as potential benefits for getting that kind of early, early input.

And I'll start with you, Angie. And then I'll go to you, Scott.

MS. KRUEGER: So, I think probably in looking at what types of guidances it might be more helpful for, at least from my perspective I think maybe more device-specific guidances would be an area where that feedback

could be particularly helpful before we start formulating drafts or, you know, the working groups start working on those particular issues. And where I think industry could be particularly helpful in that kind of initial process is kind of figuring out are there areas of the problem, you know, when we're trying to scope it out -- we have a problem we're trying to fix, or we have an issue or a topic we're trying to address, are there pieces of the puzzle that we might have missed in our initial kind of scoping out of the issue?

And so, sometimes in the drafts, when we issue a draft, the comments we get back is you didn't even address this bigger piece or this big part, or you didn't give examples in this area. And I think having industry feedback on the front end of that could be helpful so that when we're working on the guidance document, it's helping address our issues and also kind of forward looking and proactively trying to address issues that industry may have a particular interest in, I think, for a device-specific guidance, especially for those manufacturers who make those types of products and might be able to provide the inputs early on.

MS. STADE: Thanks. Scott?

MR. McFARLAND: Yes. So, I think I echo a lot of the same stuff that Angie was saying. I think for us it would be especially device-specific guidances that are focused on novel areas or areas where there really -- the industry hasn't been developed yet. I don't know if you are familiar with the highly multiplexed guidance that was released. We had a concept paper in

advance of actually even releasing the draft guidance that allowed us to get some input from industry beforehand at a workshop.

I think in situations like that where it is very novel, it is helpful to get that input early, make sure we address what the issues are, what are the stop blocks that are keeping industry from going into these sectors or where they need -- a good idea of where the regulatory process will be located. So, I think that would be the case where I think I would see the most value from getting that sort of upfront feedback. And I think we've tried to do it before, and I think we'd be supportive of doing it in the future.

MR. BEINKE: Can you talk a little bit more about the concept paper approach and why did you decide to do that? When can you use it? I mean it makes sense to me.

MR. McFARLAND: So, I think -- I'm only aware of that one. I think there might have been a second one on biodosimetry, but I'm not certain on that. But in those instances, we thought it was an unmet need that we needed to figure out a regulatory scheme, or at least an idea of what one might look like in order to encourage investment and research into developing a device on those spheres. I think that was kind of the trigger for us was that we felt like it was difficult for us to necessarily anticipate what those problems are going to be for industry.

We thought that we needed to hear those in order to know where you all saw the problems so we could work on trying to develop a

document that reflected those concerns.

MS. STADE: And importantly, if I remember correctly, in that case that the discussion paper was actually used in a public meeting to gain additional input and reactions.

MR. McFARLAND: That's correct.

MS. STADE: So, I actually feel like there's a lot of material here, and I'd really like to -- you know, I would love to have the opportunity to explore some of these issues more. But, unfortunately, there are a few other areas that I really want to turn the Panel's discussion to, particularly draft guidance documents because that issue came up several times this morning. It will continue to come up. I think we have to acknowledge at CDRH this is an area where we could do better in finalizing drafts.

But I'd like to talk just a little bit -- and this is something I didn't cover in my GGP 101, but I'd like to cover now. And I'll turn to Phil just to ask a little -- to speak a little bit about what the status is of a draft guidance document.

MR. DESJARDINS: So, I think around this table you'd get a lot of agreement in terms of what a draft guidance does represent, or at least should represent. And the intent there is that this is really the Agency's sort of first take at a proposed policy. This is not a policy that's expected or intended to be implemented within the Center or within the Agency.

I think the feedback that we've heard is that this definition or

this interpretation might not be being consistently applied amongst review staff. And that's an area that we've taken steps internally to try to address that. We've been as clear as we can at the management level in terms of indicating to people through formal training on some draft guidance documents, all hands announcements, e-mails, all hands staff meetings, when new a guidance document comes out, in terms of what this guidance document means in terms of where the Center may be going in the future, but also what it means in terms of what's going to be changing from today moving forward. And with the draft, that response should actually be nothing.

Where the rubber meets the road is really in the offices, and I think particularly in the premarket review offices where I'm at least hearing that some of those miscommunications are occurring. And one of the things that maybe I would pose both to Angie and Scott is how are those messages being communicated amongst review staff? And if individual companies or representatives, people that are here, feel like there's an issue where a draft guidance document is being implemented, are there mechanisms where they can flag that for the attention of someone else within the Agency that can try to resolve those issues?

MR. McFARLAND: So, I'll take that first. So, yeah, we definitely are not trying to implement draft guidance. If someone got the impression that we were able to use draft guidance as a source of authority for some sort

of action we're taking, we immediately step in and we talk with them. We don't do that. I think, as was discussed earlier in this work panel, I think the case where I think sometimes there's confusion within industry is that we do handle issues on a case-by-case basis still within the office. If we weren't able to handle things on a case-by-case basis when there was no guidance in place, then things would totally shut down for years of time, and that wouldn't make any sense.

But no, no one should be citing the draft guidance. We try to make sure we get the message out within our office. If you're aware that that has happened, please by all means feel free to contact me, contact your ombudsman. We'll be happy to try and step in and address it, if it really did happen.

MS. KRUEGER: The only thing I would kind of echo as part of Scott's comments are that as part of the review process and sometimes the area where we -- kind of what triggers device-specific guidances are when we start seeing, you know, the same types of issues coming up over and over in our review process. And that in and of itself on a day-to-day basis is what the reviewers are tasked with determining, in terms of safety and effectiveness of devices. And so we kind of end up in this process where we may be asking for certain types of information to get us to an SE determination, for example, in a 510(k).

And then we put out a guidance on that particular device, and

that information is in the guidance. And I think where people sometimes get hung up is, I've been asking for that information in my reviews, I ask it consistently, I ask it for every manufacturer, it's part of our 510(k) determinations, and now that it's in a draft guidance, I'm not supposed to ask for it anymore? I think we don't consider that to be implementation of a draft guidance.

And so I think we need to be careful about how we're using that terminology, especially in the context of device-specific guidances because we wouldn't necessarily consider that -- you know, we've now issued a guidance, a draft, and we can't ask for that type of information while that draft is out for comment.

MS. TRUNZO: I have a question for you.

MS. STADE: Janet.

MS. TRUNZO: Is this situation you just described more of a situation when there was an existing guidance document on a specific topic that outlined certain types of requirements, then you updated that guidance in a draft, which would still include some of those previously required or previously suggested requirements in the initial guidance, so that the draft is really not a complete draft on a new policy? Is that what this is more about?

MS. KRUEGER: So, I think sometimes that is the case. But I think -- take the example of a novel technology where we haven't put guidance out there, and we're, you know, in the PMA or a de novo for novel

technology. I mean you may be asking specific questions to get to your safety and effectiveness information. And I think what I'm trying to say is, once we've kind of formulated our thoughts about what that safety and effectiveness level is, and what we need to evaluate it, we may at that point put that information in the guidance document.

But at the time that draft is out, we're also still reviewing other devices maybe of the same type. And we would expect that that safety and effectiveness information potentially would also be included in a PMA, just as it was for previous PMAs prior to the guidance coming out. So, I'm just saying there's a little bit of a flux there as part of that lifecycle, especially for device-specific guidance documents.

MR. DESJARDINS: The way that I think about this distinction is that guidance document isn't necessarily creating or differentiating old policy from new policy. It's really codifying -- and I hesitate to even call it a policy. What it's doing is codifying into policy what was happening on a case-by-case basis across multiple product applications. And what we're doing there is trying to set expectations appropriately so that when the applications are coming in, we're not sending out the same additional information letter over and over again saying we need this type of test to meet this level of safety or this level of effectiveness or what the outstanding scientific or safety question may be.

In those scenarios, just because we issued a guidance

document and we've reviewed five files before there, just because the sixth one happens to come in at the same time that the draft guidance is out doesn't mean we're not going to be asking for that same information. But what we should not be doing is pointing to the draft guidance document saying this is why you need to submit the information. The message at that point in time should be this is the type of information we need to address this question.

And at some point in the future when that document's finalized, that's the point when it's easier -- and one of the reasons we do put out guidance documents is to make it easier and more transparent for people and for industry to know what our expectations are ahead of time. And I think that's where some of the confusion may lie. And when we hear the complaint about a draft guidance document being implemented -- and again, I'm not saying it's not occurring -- but in some of the examples when I've heard it in the past, when we've sort of traced it back, that seems to be one of the areas of confusion or an area of distinction between the Center's understanding and the individual sponsor's understanding.

MS. STADE: Hans?

MR. BEINKE: I guess I'm just wondering -- I mean I understand your point. I mean in one case where you're just codifying what the Agency's been asking for for some period of time versus it's totally new. Is there not some way in the language of that document in the introduction to say that

this is conveying requirements that are in practice? I don't know. I mean I do understand. I mean if you're constantly providing that information and to now say, oh, well, I don't have to provide it because there's a draft, it doesn't make any sense.

MR. DESJARDINS: I would defer to the Office on this, but that's not something that we're actively doing right now in terms of distinguishing those types of guidance documents. I think that actually might be a good -- a very easy way to maybe identify some of those issues. But, again, the whole purpose of doing this draft -- we've been asking for this type of information to address this question. Even when the guidance document is finalized, I don't think we're saying this is the only way to answer these questions. This is our recommendation on how to do it.

MS. STADE: Okay. So, now I do want to turn a little bit to some performance measures, if we can get metrics, what they might look like for a guidance program. And, again, this is very preliminary, but I thought we'd have this discussion.

But before I get to that, I'd just like to ask -- and this is a question for the external stakeholders. How do you think we're doing, not timeliness in finalizing draft guidance, but as far as responding to comments? And I don't mean -- I know we hear sometimes, you know, one of the ways guidance documents differ from rules is that we don't have this one-to-one response in the Notice of Availability that says we received this comment and

we addressed it this way.

But just how and whether you think when a final comes out it seems to be responsive to the comments we got on the draft. And I just want to open it up to any of our external stakeholders to comment on your experience with that.

Janet?

MS. TRUNZO: A lot of the work that is done within my team is responding to guidance documents that FDA issues on a regular basis. We track whether our comments have been accepted in the final case, in the final document when it comes out. And we -- you know, from my perspective, I believe that many of our comments are listened to and are placed into the final product.

What I would say is that it's not a hundred percent of the time, right? And we wouldn't expect that to happen. A hundred percent of our comments would be a hundred percent of the time accepted. However, because we feel as though the -- if the comment is done in a very, you know, rational way where we present why it should be changed, I believe that FDA gives us a good hearing on that.

MS. STADE: Any other perspectives on that?

Okay. So, let me talk a little bit about some of these questions surrounding how many, how many guidance documents should we be issuing. And I assume folks haven't thought about this in terms of a number, but

nonetheless, I'd be interested in hearing, you know, from the perspective your organization what you can actually respond to. And even assuming with or without some of the improvements we've talked about that would make guidance documents easier to respond to and easier to sift through the ones that matter to you versus the ones that don't.

And then just let me give a historical perspective because -- I joined CDRH in 2009, and what I was used to hearing about then was, you know, your process is broken. You don't issue enough guidance. And we have actually -- we heard this morning from Paul Brown, and we've heard elsewhere from some of our industry stakeholders, you know, slow down, guys. We don't have time to comment, or we think that -- and we've heard less of this, but I wonder if this might be beneath the surface. You know, change is good, but managed change. And I think sometimes folks do get nervous.

And I'd just be interested in hearing if folks have ideas about -- and this may apply more to the cross-cutting guidance documents -- you know, how many guidances, programmatic guidances can be digested in a year? Or how we should start thinking about, you know, getting the program to the right size where we're issuing -- we're rolling out changes in policy in a way that's manageable. I don't know if folks have any thoughts about that?

And I'll be stunned if -- oh, good.

(Laughter.)

MR. HALL: I have thoughts on anything. A couple of just observations. If a guidance is needed, particularly for patient benefit, whether it's improved access, improved safety, whatever, I think that is frankly a no-brainer. It's got to come out, and if there are a lot of them, that's life. There is a need in the ultimate customer that we all serve.

If it's efforts to improve, streamline processes, those are valuable. There, I think you -- but they're not a direct patient benefit. There, I think you can take a more measured approach, saying we've got a bunch out there, let's get through those, and then move on. And as part of that, particularly when you get the programmatic guidances, they can be interconnected.

And so, in those situations, I think you do need to think through or I suggest you think through the progression of how those fit together. And if they are linked, they may need to be out at the same time. If they are not, if they're part of a sequential process, you may want to walk through it sequentially. But if there's a need for it, I wouldn't worry about the number even if, you know, it causes a lot of work for us.

MS. STADE: Yes?

DR. BRINDIS: Building on Brother Ralph's comments, I wouldn't be so focused on the number. I think it's -- you know, one has to examine what the actual need is. And maybe that sort of blends back to your earlier question in trying to figure out performance measures for yourself. Because

the performance measure right now that you have, which is number and time from initiation to completion, isn't really the performance measure that I suspect that you're all really trying to find.

And I was trying to come up with a couple off the top of my head. The first two are bad; the last one's better. One of them might be just understanding the comments, the volume of comments, and how they've helped you. And the other, which I haven't actually heard from yet, and I'm sure you know the statistic cold, is how many guidance documents were actually initiated from outside requests versus inside requests. That kind of interests me in terms of the process.

But maybe in trying to come up with performance measures maybe having a -- abuse your external and internal stakeholders one more time and give a one-year follow-up questionnaire where you ask them about the document in terms of its usability, its help, and its impact. And maybe that may turn out to be a decent performance measure in terms of assessing what you're trying to accomplish.

MS. STADE: Janet?

MS. TRUNZO: I think those are great ideas because it's really -- okay. It's really about -- it's not about the number, I don't think. I think it's more about are the right guidance documents being developed in the right priority. And you have to go -- you go through the exercise of prioritizing the list at the beginning of the year. You go through the exercise of getting

comments back from stakeholders to see if that's the right priority list, and then you go from there. Were you able to achieve the goal of getting those priority documents done? I mean if they're on the list, there's a reason for on the list. They meet some of the criteria that Ralph just described.

So, I think that's where the focus is. It's not the number. It's the right documents out at the right time. And I have one other comment about measures.

One of the measures -- and it looks like Nancy went through a lot of effort to go back in time to see how long it took for a draft guidance to become final. I think that's important to continue to make those measurements because it does give you an assessment of your performance in getting drafts to final. However, what I don't know is how many drafts are still in draft that have not yet gone to final. That is a number that I think is important to understand the overall because the number we saw was just the ones that actually did go to final. Is that correct? So, I think the measure should be a little bit expanded in that regard.

MS. STADE: Paul?

MR. BROWN: Well, I still stand by there's too many, as far as nonprofits go, to actually do a good job of looking them over. But I think what I 'm hearing when they're saying -- what Ralph and Janet are saying that, but the numbers don't matter if we prioritize, I think that's true. If we have tiers on there, which you do, it would allow us to focus on the high

priority ones. Maybe we can't look at all of them. We certainly can't look at all of them, but by prioritizing, we basically are funneling that down a little bit. And that is very helpful for us.

MS. STADE: Hans?

MR. BEINKE: Yeah, I mean I agree with everybody else that it's not about the numbers. But, for me, just having that priority list is not enough. I'd like to see almost a map that shows what your vision -- hopefully, ultimately would be our vision -- of what the next three years, five years are going to be like, and then get what the priorities are within that, I mean, if you had that map. And maybe it's too big. I don't know. But within that map, you could do all kinds of things of color coding which ones are in draft, which ones are out of date, and -- I mean I deal personally better with visuals, you know, that I can look at this whole thing and see this is what the map is, this is what the plan is.

MS. STADE: Leslie?

MS. KUX: I guess I have a question for the external stakeholders. So, I was smiling because one thing I see is how quickly priorities change and shift and so -- for many, many different reasons. And so I guess what kind of frequency of updating would be useful for you all?

You know, we could have a map out there, you know, as a nice visual -- you know, a map. But, you know, the day it goes up something could happen the next week that would throw it all into disarray, or throw a part of

it into disarray. And what would your expectation be about our communicating with you about that? Especially, say, if it was an emerging, you know, situation involving, you know, a lot of adverse -- I mean, you know, with a -- you know, that might, you know, result in new guidance or enforcement or, you know, sort of a public health situation, I guess.

MR. BEINKE: Yeah, I mean I certainly understand the problem of constantly trying to update this. On the other hand, if you had this one-off situation, it's on your overall map, or even not on the map, and you know it's an issue, then is it that difficult to have a revision on that and have it revision controlled?

MS. KUX: Well, it would take a lot of -- I mean one of the things I've learned is that it -- because priorities do shift it actually -- it takes a lot of resources to keep up, especially across a large program area. So, that's just something -- if you want an accurate map, then you're taking --

MR. BEINKE: Right.

MS. KUX: -- resources away from the guidance program.

MR. BEINKE: Right. And I think you can go crazy with it. I mean to me there's a difference of, well, we can easily update that. We can take if off the list for whatever reason. That's easy versus saying our program is going to require us to update this once a year or every six months. Those are two very different things.

MR. DESJARDINS: I don't want to get in the way of a really

good conversation and dialogue, but you guys are stepping all over my presentation that's supposed to take place in a few minutes.

(Laughter.)

MR. DESJARDINS: So, I'd like to either make a suggestion that I can run through my slides and give you guys a snapshot of what CDRH's prioritization process looks like right now to continue this conversation, or we can sort of put a pin on it, let me give you that presentation again quickly so we can get back to the discussion. Because I think seeing what we're doing, allowing you to comment on what we're doing, how we can improve that or how we can expand on that, will really help sort of crystallize the recommendations so we can take some concrete steps moving from this meeting.

MS. STADE: That's great. Actually, I think there are just two -- just a couple -- a question and then an observation. I just wanted to wrap up on this part of the panel, and then we'll -- you can turn to the prioritization presentation.

And I have to do this to you, Heather. I hope you don't mind, but you're the one person on the panel who's been both places within CDRH and now on the outside. And I just wonder if you could comment, you know, both for the benefit of those of us internally and also for the benefit of the folks externally, just your perspective on the guidance process and maybe how it's changed since you've left from the government.

MS. ROSECRANS: How the process itself has changed, I still see it as, you know, a great way to communicate to many people and get the messages out. But I found when I was here, and I found now -- and I definitely want to hear the latest on the process from Phil -- it can be extremely frustrating on both ends, and everybody's trying to do the right thing. And so improving that process and having the ability to get the comments more quickly -- I think what I found most frustrating were the timelines, where you would work very much on something for a -- and then you wouldn't hear about it for a year or two, or it would get pushed back.

And I think there are more and more guidances coming out now, but that the timeline of how to comment and how to predict what we'll comment is crucial.

MS. STADE: So, I just want to summarize a little bit or just -- not summarize so much as make an observation, which -- you know, these are -- I'm very sincere when I say this, that I think a lot of the suggestions for process improvements are great. I do think they have costs, costs probably in productivity and also in timelines and just something to think about.

You know, the more processes we build in, you know, one hopes that they create greater efficiencies, but every process -- particularly when you're in government, you know, if you're talking about additional processes going through the *Federal Register*, there's a time lag just to get something in the *Federal Register*, even a very simple document, then

receiving comments, collating comments. Is it possible that at the end of the day that input will be so enlightening that the process will be improved?

I think I'd want a pilot in a few cases and see, and see whether for specific guidances or maybe specific types of guidances the net result is, you know, a better process and a shorter process. Or is it just, you know, as Ruth demonstrated for us, just stretching things out further? And I suspect it could go both ways, depending on the guidance. That's my belief at the outset.

Anyhow, with that, thank you, everyone, for that conversation. And I'd like to turn now to Phil's presentation on prioritization, and then the panel discussion will also focus on prioritization.

MR. DESJARDINS: So, Nancy, does it make sense to take the break now and maybe let me do my presentation when we get back and then we can go right into the conversation?

MS. STADE: Sure.

MR. DESJARDINS: I think we're a little over where the agenda time was, and I think might help facilitate sort of where we left off in the discussion. And that way we don't have the pause for -- right in the middle of that piece of it.

MS. STADE: Oh, I'm sorry. Were we breaking now or after?

MR. DESJARDINS: I think we're supposed to break after, but I was wondering should we do the break now --

MS. STADE: Okay, sure. Sure.

MR. DESJARDINS: -- and then I can push us forward into that conversation?

MS. STADE: Okay. Folks, you have a break.

(Off the record at 1:46 p.m.)

(On the record at 2:02 p.m.)

MS. STADE: So, we 're going to get started on the final component of today's agenda. And before we return to the panel discussion, Phil Desjardins, the Associate Director for Policy at CDRH, is going to present on CDRH Guidance Prioritization.

MR. DESJARDINS: So, as I mentioned before, I think the discussion was heading towards this direction already, and I think this is a very relevant portion of the guidance development process that I think we should spend time exploring today.

I also recognize the internal prioritization process has a little bit of inside baseball, and it's not the internal process that I think we're going to get a lot of comments on. But I think understanding what that process is will help both the panel members here and the audience members sort of understand what it is that we're doing right now and how maybe we can build on it to improve, and be able to get a little bit more feedback from our stakeholders and maybe leverage some of the things we're doing now to build towards the future.

So, I'm going to try to go through these slides, or through the presentation, and provide you the information, but I'd love to jump back into that discussion as quickly as possible because I think we were making some real progress. So, the first piece basically is to acknowledge that there is a prioritization process that's taking place within CDRH.

First of all, we are tracking all guidance documents that are currently under development. This is not necessarily the priority list. This is just the list of guidance documents that are under development. We've got tracking systems that show us where they are in the process, not at a super granular level, but at the different milestone levels. Are they still in workgroup development? Have they been sent up to the Office for office clearance? Have they been cleared at the Center level? Are they going over to OCC? Those types of things. And just to give you guys a sense of the scope that we're talking about, there's 87 guidance documents on that list right now.

There's a second list that we capture, and actually, it's not so much a second list, but it's a way that we break down the list. And when we look at the list of documents that are being worked on currently, we try to make a single decision. Is the guidance document a prioritized document or a non-prioritized document? And the criteria that goes into that is not super explicit. It's sort of a "we know it when we see it" where we've got some -- there are external factors associated with it, and where does it fall within our

priorities? And I think the question really is as simple as that. Based on the numbers that I'm showing right now, it appears that the way it plays out is that about one-third of our guidance documents end up getting prioritized.

The prioritization process predates me to a certain extent. I joined the Agency or the Center back in 2005. At that point in time there was a priority list, but it didn't have the level of detail and the level of distribution that it has right now. When I joined the Center in 2005, the priority list wasn't available to all members of the Center. It was sort of a list that was developed by the Deputy Center Director or the Center Director's Office and discussed with senior staff members, but the staff that were working on guidance documents didn't necessarily have a good sense of whether or not their guidance document was prioritized or not, or where it fell on the Center's priority list.

In some instances, you could always get a good sense of what were the Center's top priorities because those were the ones that we were speaking about and getting asked about. But outside of sort of that top 5%, it was very difficult to discern where a particular document and particular document you were working on fell within the Center's priority list.

So, when we re-envisioned what the priority list would look like, we asked ourselves what was the purpose of creating this list? And I've bulleted a couple of the different items that I think this list or this process actually accomplishes.

The first is that it gives all staff a snapshot as to where different documents fall within the priority list and what the top priorities of the Center are. And not just from a policy development perspective, but a lot of our guidance documents also mirror some of the other priorities that the Center has. Looking at our strategic priorities, a lot of those priorities also match up to a guidance document that's under development.

It also allows external staff, both internal and external to the Center at least, looking at the Agency, both within the Office of the Commissioner and other Centers, to know what the Center's priorities are and allow them to prioritize the work that they're doing with us and for us. Particularly sort of our work with OCC, our work with Leslie within the Office of Policy, if they know -- and oftentimes there are competing resources. Two documents may be sitting on one individual's desk, and they need to know which document should they be working on first. And this list helps them make that judgment without necessarily the need to come back to us for a specific ask on that.

It also allows more predictability on prioritized guidance documents. As Ruth mentioned earlier today, the overall development process is very elastic. And I can think of a couple examples where we've gotten guidance documents that were draft guidance documents out from initiation to publication in as short of -- I think 2½ months might be the record that I've seen. But those really reflect high-level priorities but, more

importantly, particular or at least identifiable public health needs.

But when something's prioritized, I think the takeaway is there are savings from a timing perspective that can be made, and I'll go into a little bit more detail a little bit later. Right now, it's know that something's a priority allows us to exercise some of those additional controls in making sure that timely progress is being made. And, again, it allows for a greater visibility across the Agency so that there is a single document that we can share outside of the Center so that the rest of the Agency knows, number one, what we are working on and also what those priorities actually are.

The second big takeaway I think from the purpose of the prioritization list is that it's not intended to halt development on non-prioritized guidance documents. And I think that's actually a pretty important part that I'd like to speak a little bit about.

As we've been tinkering with the guidance development process over the last seven or eight years, one of the things that we did look at was should we be focusing all our existing resources on just those priority guidance documents? If they really are the Center's top priorities, should we be focusing our resources and make sure that those are the documents that move forward and reevaluate what those priorities are every year so that we hit all the things that need to be touched?

And I think it was 2007, maybe 2008, we changed the nature of the priority list. And what came out of the Office of the Center Director --

and this pre-dates Nancy -- was that a prioritization list was developed, it was a much shorter list, and the direction out to the Center was we're going to be focusing all our resources on the priority documents and we're not going to be formally reviewing the non-prioritized documents. And what our hope was, was that we'd see increased time to issuance on those priority documents, and if it wasn't a priority, we could readdress our priorities the following year.

I'm not sure if it's fortunate or unfortunate, but what we learned from that little experiment was we didn't see a lot of savings on those priority documents. What we did see, however, was a big lag or a big delay on the non-priority documents. We issued roughly the same number of those priority documents and the time to issuance was roughly the same, but the number of guidance documents that came out that year and the two or three years following that were lower. And, at the end of the day, we didn't think that there was actual savings that were occurring.

When we did some after-action analysis, what it turns out is a lot of the documents that are being developed are not necessarily being developed by the same staff throughout the Center. You've got some staff that are focusing on those cross-cutting priority issues, and then you've got completely different staff that might be focusing in on the lower priority documents. One of those are device specific or programmatic specific documents that really have a distinct number of subject matter experts that

were working on those. And by asking them to stop working on those documents, they weren't re-devoting their resources to other guidance documents. They were just working on some of their other tasks that they had as part of their responsibility.

So, I just wanted to throw out that we did try focusing on just priority documents, and in my opinion, at least, I don't think there was -- that was a successful pilot program.

So, I wanted to talk a little bit about what the prioritization process actually looks like in the Center right now. First, we've referred to it a couple different times as an annual prioritization process. And that's accurate to a certain degree. At a minimum, once a year the Center sits down and does -- goes through a does a prioritization review. And this is sort of the formal process where we take an inventory of everything that's under development and formally ask the Center and the Offices and the Agency to weigh in on what priorities should be and what priorities actually are.

But what I'd also like to point out is that this is a list that is dynamic and is updated, both in real time and then more formally on a quarterly basis. We do collect this information again at the beginning or middle of each quarter so that we are -- we're accurately reflecting -- so this list itself, the piece of paper that Center staff have access to accurately reflects both what's under development and which of those documents are priorities for the Center.

So, the process itself is managed out of the Office of the Center Director through a combination of Nancy's efforts, my own, and some of the other staff that work in that organization. And although it's managed by the Office of the Center Director, it's really a collaborative process with the Offices and to some extent organizations outside of the Center as well. OCD will organize the list of all the documents that we know that are under development and then reach out to the Offices to get some background information on those documents.

The first check is just to make sure that we've actually captured all the documents that are under development. I told you our list was 87 right now. I wouldn't be surprised if there's one or two other guidance documents that staff members believe they either want to be working on or should be working on. So, the next time that goes out, they will see the list, and if something's missing from that list, they'll let us know, and we can add to it.

The second piece is we want to get an initial prioritization recommendation coming from the Office. While Center management has a role in identifying top priorities and also competing priorities, oftentimes, and hopefully ideally, those priorities are going to match with the priorities of the Offices themselves. Where it gets a little bit more -- I don't want to say difficult, but OCD management becomes a little bit more important is when there's competing priorities amongst the Offices.

As we've alluded to before, we've got both of our premarket offices represented right here, and I think it wouldn't be a surprise if they represent the lion's share of the guidance development efforts that are within the Center, but it's not at the exclusion of some of the other Offices who may be issuing two or three guidance documents a year.

And part of that process is also trying to gauge, or at least identify, what the potential impact on stakeholders will actually be. And oftentimes this is where we're applying our best guess, or maybe our best analysis, as to what that might be. But that's really important at this Office and Center level in terms of identifying what those priorities should be and are.

The next step in the process is OCD preparing a draft priority list that we then distribute to the Offices. Then we sit down with senior staff -- and this is representation of either Office directors or delegates for Office directors -- and discussing what the priorities should be. So, again, if ODE, for example, comes forward with a proposal of 20 priorities, it's then up to the Office of the Center Director and the other Offices to sort of call them and ask for a little bit more information on what those documents are and why they should be Center priorities.

And this is often sort of where the list is finalized. It's other Offices and Office directors asking each other and reaching agreement in terms of what those top priorities are. And it's not really a numbers game

where ODE is allotted 17 priorities and OIR gets 16 and then OSB has 2 to work with. But there really is a discussion that takes place at that management level to think about what does the Center really need to accomplish next year to make progress on these policy initiatives?

At the end of the day, the proposal list is then submitted to the Center Director, who can finalize the list and may make a couple of modifications at the end. And then that document is available to all staff. It's distributed to Office directors and senior staff, but it's also available through our guidance development internal webpage that the Agency maintains.

The effect of the prioritization process is also important. When we look at what the intended effect is back to the purpose, and what it actually does, ideally they should be the same, and I think they are. First, it allows the Center to devote the appropriate internal resources to development. As Nancy alluded to before, we've got a rough estimate of about one FTE per guidance document. And how we allocate that FTE and the timing of the allocation can often make a big difference on how quickly that guidance document comes out.

I manage a staff of policy advisors, who some of their chief responsibilities are policy development. And often that entails developing and writing guidance documents. If a document is a high priority, or a particularly high priority, their full-time job for two or three months at a time could be developing that particular document. And, in that situation, that's a

document that we would expect to move forward to issuance rather quickly. If a guidance document is not prioritized, it may be the case where there's one subject matter expert who's devoted to working on it, but they can only work 5% of their time over the course of the next year and a half to developing it. And that might be on the longer end of the development spectrum.

Again, we also look at competing resources at other parts of the Agency, whether it be OCC, organizations within the Office of the Commissioner, or within the Center itself.

And one of the other purposes, or effects of it, is allowing us to set internal guidance expectations. There's a couple different documents or public facing documents that you might see this occurring. The first is -- internally, at least, the way we monitor this is continuing to ask and setting up internal milestones or checks to see what's going on with the development process to make sure that we're on track to meeting our internal milestones and getting these out when we expect them to.

I think more relevant for you guys is what the prioritization process can look on a public facing expectation. And there's a couple different areas where I think you're more likely to see guidance expectations. I think as a general rule, for a non-prioritized guidance document at least, the Center and the Agency is probably going to be a little bit cagey in terms of identifying expectations from a timing perspective. You're unlikely to be able

to peg me down as saying this is the date that we anticipate any guidance document being issued, unless we've already made sort of a conscious decision to identify a milestone.

And those milestones are usually identified in one of two ways. The first is through our strategic priority commitments. And over the last four years, I think every year we've come out with a strategic priority document, and I think in each of those four years, there has been at least a couple documents, or a couple guidance documents that have had specific dates associated with them. The reason we're able to identify those dates is because they've been identified as priorities, and we've worked a little bit closer in terms of crafting and analyzing to make sure that our development plan is accurate and that we've got the resources to make sure that we're moving forward and making adequate progress.

The second is going to be a little bit less formal, but in terms of our legislative commitments. The Center and Agency representatives are often called down to the Hill to either testify formally or to provide informal information on some of the different activities that the Center and the Agency is working on. And if we know that there are hot topics that we're likely to be pressed on, or we're going to be asked for what our expectations are, we can make sure that those are priorities, and again, that we've got greater oversight in terms of the development process itself.

What I've provided here -- there's a lot of words on this page,

and I've copied this from our priority list. What I wanted to do is sort of show you the language that's used to frame what our priorities are and what staff is seeing when they see the priority list. And so, this top bullet is copied and pasted from that list to sort of show how we're framing what our priorities actually are.

The second bullet is intended to show sort of the progress that we've made. It might not be -- the numbers that we're looking at is, I want to compare draft to draft and sort of our progress that we've made over the last eight months on our priority list. So, in September, or I guess it was actually October, we had identified 25 draft priority guidance documents. And since that time, we've issued seven of them, and we've added one new document to that list. On the final front, there were 18 guidance documents that were identified as priorities internally, and 7 of those have been issued. And, again, one has been added to that as well, bumped up from non-priority to priority.

Non-prioritized guidance documents, I wanted to do the same thing, provide you with the language that we're actually using in communicating what the list represents. And, again, the intent is not to tell people that they should not be working on that, or that these are not valuable document for the Center, but it's just to let people -- give people a snapshot into what a non-prioritized guidance document actually means.

And, again, just to sort of compare our progress on non-priority

documents, we identified 35 draft non-priority guidance documents; we've issued 9 of those, but added 16 to the list. It also flagged that two of the things that were identified as non-priority guidance documents since that time have been removed from the list, and we've identified that continuing to invest resources in developing those guidance documents was no longer warranted. On the final front, we had identified 13 non-priority final guidance documents, 6 of which have been issued that time, and 5 have been added to the list.

And, again, sort of the distinction between draft and final here, we've talked a little bit -- or, quite frankly, a lot about the Center's need to make better progress in finalizing those draft guidance documents. But, again, I think if we lumped every single final guidance document into the priority list, we'd lose some of the advantages and some of the effectiveness of having a true priority. And I don't think it's -- I would never say it's not a priority to finalize those guidance documents, but there are some documents that are more significant and are going to have a bigger impact, internally and for our stakeholders, and that warrant a prioritization.

I just also wanted to mention the annual MDUFA III commitment webpage that we update on an annual basis. Our MDUFA commitment in MDUFA III was to identify an A list and a B list, the A list roughly signifying our intent to issue those guidance documents in the current fiscal year, and the B list reflecting our efforts to continue working on

that, but there was a less formal commitment to get those guidance documents out in the fiscal year.

And I would distinguish the external list from the internal list in a couple different ways. I think, most importantly, the criteria that's been used to identify the MDUFA III commitment is looking at what we're actually going to issue in the current fiscal year.

I think one of the things that we haven't touched on right now is I've heard anecdotally in the past that knowing that a guidance document is coming, but not actually seeing what it's going to say and what the policy is going to be, could potentially have a -- it could stifle innovation, or it could cause industry to maybe hold back either on development or submitting an application in those areas. And I think that's one of the things that at least internally I've been cognizant of. I'd like to tee that up for maybe discussion later. But there are some distinctions in terms of how we identify documents from the internal list and put them on the priority list.

But that's sort of the snapshot of what the internal process looks like. Again, I think the internal process is very relevant to how CDRH gets documents out on a day-to-day basis. I wanted to give you guys insight into what that process looks like, but maybe see if there's -- some of the things that we're doing we could leverage to help foster the type of discussion I think we've already had right now in terms of getting better participation in the development with our stakeholders moving forward.

So, with that, maybe do we jump right back into discussion?

MS. STADE: Let's jump right back into discussion.

To start with, yeah, if Sharon and Heather would join us on the panel? And we have had a couple of changes in our panel for the afternoon. Leslie Kux had an emergency. Don't worry, folks. She said she'll be back, but she did have something she needed to tend to, and she hopes to be with us for the last part of this panel. And also Janet Trunzo had to leave, but we do have Sharon Segal, the Vice President, Technology & Regulatory Affairs for AdvaMed.

Let me just give you an updated timeline because we're a little bit behind. Let's try to have this Panel run from now -- it's about 2:20 -- to 3:00. That'll give us from 3:00 to 3:45 to answer questions, and then I'll just take a few minutes to wrap up.

So, for now, let's turn to questions on prioritization process. And I'll just start with one question I have. It's something we scratch our head over a little bit. We do have a prioritization process in CDRH. It's not perfect as far as providing notice about the guidance documents we are working on, but it does provide some information and also opportunity for input on our priorities. And what we find, actually, is that we don't get a lot of comments on that solicitation for input.

And I guess I'd like to hear a little bit more about why that is. Sometimes we find that we get comments on our FY 2013 priorities at about

September 30 of FY 13. Or we find that we just don't receive a lot of comments. And I guess I'd be interested to hear how we could make that solicitation and the input more meaningful. And we have heard about that a little bit, but we're always interested in hearing more.

Hans?

MR. BEINKE: I guess I'm surprised. I mean Ralph and I were both looking at each other. I mean I thought we were providing input. It sounds like we need to do a better job.

MR. DESJARDINS: In terms of the formal docket, quite frankly I go through that docket at a minimum every quarter, and I've got it set up so that I'm notified. I think in 2013 we got a total of three comments to the docket, and in 2014 we got two. AdvaMed does comment every year. And, quite frankly, those comments are very helpful. They address the list in its totality. Some of the other comments that we've gotten, we got one comment I think -- I don't remember if it was this year or last year -- from a standards organization providing requested changes to a very specific document. Again, that's the formal mechanism by which we do get feedback on what the priorities are.

I'd also mention that interactions like this, more informal interactions, whether they be advisory committee -- just the feedback that staff get from stakeholders is fed back into the process and built into the prioritization process. It's just at a much less formal nature mostly.

MS. STADE: So, any follow-up comments on that?

MR. BEINKE: Again, I'm not sure what to say. I mean I think I need to talk to the organizations that we're involved -- that I'm involved with. I mean you're talking about AdvaMed -- fine. Coalition, MITA, if we're not active enough, then apparently we need to get more attention to it.

MR. HALL: I think it's good feedback for us. Is there a particular form or -- I mean how can we make that feedback most effective and beneficial for you?

MS. SEGAL: I can offer what we do from AdvaMed is every year we take a look at the list and we solicit input from all of our member companies what's important to them, what should be moved between lists, and add guidances that do not appear on the list that we think should. So, that's the format we take, and it's very short and sweet.

MR. DESJARDINS: I think the most helpful information from my perspective at least is two pieces. The first is, if there's something that's not on that list that you would either expect to see there, or maybe won't even expect but want to flag for us, this is a great way of putting it on our radar, because hopefully it is on our radar and it's something we're working on and it just hasn't made it to that level of the priority list. But if it's not something on our radar, it should be.

I think we have a comment from the Internet?

MS. PIRT: Could you please explain which docket you are

speaking about? Is it the comment website or just comments in general?

MR. DESJARDINS: So, I don't have the docket number off the top of my head. Actually, I might have it in front of me.

So, there's a website -- and, again, I hate to point to Google for the best way to find information on our website, but if you Google CDRH annual prioritization list, every year we update it -- it's usually around October 1st. I think with sequestration this year it came out a little bit later. But it provides an A list and a B list, and the docket number is FDA-2014-N-0530. And it's a public docket. The comments that come in are publicly transparent. You can look in there to see who has commented. It's a mechanism that we would love to utilize more, but we're getting limited information coming through there.

MS. STADE: And so, for folks -- after this panel discussion, we will have additional opportunity for question and answer. And I'll also just throw out to the panelists, I'm aware we might not be covering all the topics that you think are most critical to cover, but during the question and answer phase there should also be opportunity for panelists to raise specific issues that possibly we didn't cover during these discussions.

MR. DESJARDINS: Maybe to go back to some of the conversations I think we were having before the break, one of the things that that website does do is identify multiple different ways of getting feedback both on priorities, but also on content of guidance documents themselves.

And I don't think -- one of the things that we haven't discussed thus far is industry's ability to submit not only guidance suggestions, but I'm going to say proposed guidance documents to the Agency.

And that's a specific request that's on that website and the FR notice that goes out with it, but I don't think we've had a lot of submissions. I think OIR may have a couple of examples that maybe are worth going into, but maybe I want to sort of tee up if people thought that was a useful road to go down with our discussion.

MS. STADE: Ralph Hall?

MR. HALL: I do think it's useful. I would expand your comment to all stakeholders. It could be useful for them. I think what would be helpful, if there was a better understanding -- and perhaps I missed it -- of how that process should work, where it should go, how it will go through the process, what the interactions will be, et cetera. And my only other comment, for those of you that have tried to do it, writing guidances is really hard work. I mean it is not easy.

MR. DESJARDINS: So, I think your answer in terms -- or your question in terms of what's the process, and I think you're right. There is no identified or articulated process right now. I think the examples that we have had have come in -- they've come informally, but it's been through sort of this is what we want to do, let's take a stab at it and submit it to the Agency and see what happens. But I think, again, it creates resource to develop the

process, but that might be an area where maybe we get more bang for our buck than working on one guidance document, develop a program where maybe we get an exponential effect.

MR. HALL: And just to build on an earlier comment of Nancy, this may be something to pilot.

MS. ROSECRANS: And if I could just add to that as well, I think what you're speaking to, Phil, is you've described the internal process, but it would be nice if there were a more specified process for external stakeholders exactly directing them how to comment on the prioritization. Even though it's there, how to read, kind of walking us through. But also, I think even more importantly, the two things stakeholders care about are the timelines. So, what would be the exact timelines?

So, for example, if you have a draft out there, as I think -- we've talked about drafts. What does it really mean when it's a draft? And is it in effect and is it in a deficiency letter, et cetera? But if a draft has been out there for several years, would there be a timeline, like a year, that that draft is out there and then it's either updated or something's happened with it, so that folks can predict how long it might be a draft and when they could expect the final. And I know that's much easier said than done. I know that.

But I think the process things -- and the other point would be, how does someone outside the Agency, if they have a letter that mentions a draft guidance or the time has gone on, who do they contact? Oftentimes,

it's awkward to contact the reviewer directly. You know, Scott offered to contact him or contact you or, you know, have a discussion to make sure they understand that process and what they could do.

MR. DESJARDINS: So, at the Center level, I'd like to point -- Angie, why don't you jump in because you probably get most of these.

MS. KRUEGER: Sure. And I think, to echo Scott's comments -- and he may have made them more directly for OIR -- I mean, I think ODE's been very direct with our staff that they shouldn't be citing draft guidances in deficiency letters and things like that as well. So, I think if you are seeing that, I would encourage you to reach out to me for ODE just as Scott mentioned, you know, reaching out to him for OIR as well.

MS. STADE: Paul? Oh, I'm sorry. Go ahead.

MR. McFARLAND: I just wanted to add one thing. And, again, I would reemphasize, especially -- I understand that you all value your anonymity. You can reach out through the ombudsman as well, and that provides a little bit more of a -- I guess a shield between you all and us, so if you don't feel as comfortable talking to us directly.

MR. HALL: It's not usually a problem, I don't think. We're not bashful.

MR. BROWN: I think that I use the lists in a different manner -- I'm sure I do -- than industry does. When a list gets published, I just take a quick glance at it, and I'll highlight things. And it's kind of a flag -- to flag that

this is coming up for me to pay attention to. So, some of the ones I flagged were like the de novo classification process, the 510(k) program evaluating substantial equivalent, and stuff like that. Not that I'm going to send you comments about the prioritization list, but I know that's going to be coming out in the next year, or likely to come out. So, I think I use the lists a little bit differently.

MS. STADE: And so let me just -- Paul helpfully shared the *Federal Register* Notice with me, and it looks like the docket number is FDA-2012- -- so it's the same, I guess it's the same docket every year -- FDA-2012-N-1021.

Hans?

MR. BEINKE: If I can expand on Heather's comments, I mean I agree with you very much that I mean when we hear about the internal process, I'm a bit of a fanatic on flowcharts. And so, having flowcharts even with swim lanes, if you've got multiple organizations, so that you can see that it goes from this group to that group. At what point do outside stakeholders become involved? And that's not just for this. It's for some of the other processes too. I think that it's a lot easier to understand and make sure we understand than words. I think words are misinterpreted.

MS. STADE: And let's just -- I wasn't going to step out of moderator role, but I would for just a minute. And when we talk about timelines, it is -- it's very hard for us to predict how long a guidance is going

to take. And I'd say, you know, we do a better job with the very high priority guidance documents because we put a lot into getting those out, sometimes. The fact that they're high priority means they take longer because people are very interested in them.

But that's not to say that we couldn't do a better job. I mean I could imagine something more like a performance goal than saying every guidance is going to -- you know, this is how long this guidance is going to take -- something like a performance goal. We anticipate we'll get out this many within this amount of time. That's something that, you know, particularly as we have better data we might be able to develop.

MR. BEINKE: So, when I -- and just to be clear -- and maybe that wasn't related, but when I'm talking about flowcharts, I certainly wasn't suggesting that there be a time frame put to everything. I'm just trying to understand steps. If there's a time frame that has to be met, can be met, then okay. But I understand that many times it cannot be.

MS. STADE: Ralph?

MR. HALL: And two thoughts here. One is, I think, Phil, you mentioned there's an internal tracking to major milestones of where the 87 guidance documents under the development, where they stand. If it's possible to make that public, I think that would go a long ways towards helping people understand the process, where things are, what to expect, et cetera.

The other thought here is to take a look at the guidance documents, maybe they've gone final or whatever, and try to understand the reasons for any time delays. And, you know, where are then the places where we may be able to make improvements. Some of them will be outside of CDRH's control. If it's hung up at OMB, you know, we can all sit here and say, you know, knock yourself out. Right? That's not CDRH. Okay?

Or is it that there was a major conceptual issue in the guidance document? Or, you know, was it a situation where there was a new statute, a new case decision, new law? But understanding the reasons for the time, I think, would be very helpful to help us then as a community address those issues and streamline and improve where possible.

MS. ROSECRANS: And I --

MS. STADE: Heather, then Sharon.

MS. ROSECRANS: And I agree with Ralph and what Hans was saying. What I'm saying about the timeline, again, would be let's say non-priority guidances, you would expect a draft generally in two years. And then there would be some kind of update, if it weren't two years, because obviously everyone is not -- like the performance goal that you're referring to I think would be ideal. And also the visuals that Hans and Ralph mentioned in his talk, you know, we all appreciate that you'll improve the website, Google or whatever, however you get it. But improving the CDRH or the FDA website, but separating the draft and the final guidances just as a visual, I

think, has a big impact.

MS. STADE: Sharon?

MS. SEGAL: One other issue for prioritization that I think is important to bring up is that if there's a final rule that promises accompanying guidance and it's a year later and it still hasn't happened, that's a problem because you need to implement the rule, it's gone into effect, and yet there's no guidance. The *Federal Register* Notice promises we'll address this in the guidance, and there you are having to implement without the benefit of that guidance. And I can give you some examples, but I think everyone has their own.

MS. STADE: We're aware of at least one. So, I have the feeling for some folks the idea of the annual call for prioritization input, you know, they may not be familiar with that process or may not have been using it. But I'm going to put out anyhow, you know, whether there -- are there other additional processes or additional sources of information that we should be considering as we develop our annual priorities?

Ralph?

MR. HALL: I think we -- let me throw out two ideas. One is, a meeting such as this where you can have a dialogue where you can hear different perspectives, et cetera, I think would be very useful. Secondly, to build on I think a point Hans made, if there is a map, or whatever it is, that lays out -- and, again, I don't know the time -- let's say three years, I think

that would be very useful as well.

And let me use an example in order to give the Agency some kudos. When they started the reassessment of the 510(k) program, there was a work plan maybe -- different visuals. Say, okay, I can see the items or the activities that are going to take place. I can see how they fit together. Now, there are going to be changes for public health reasons, for statutes, or for whatever. We understand that. But if you can have an overall perspective on where the next, say, three years are going, I think that would help all stakeholders see the pattern and then understand, you know, where the important activities to them will be taking place.

MS. STADE: So, this is a little dangerous, but I'll ask anyhow. Ralph, you gave us your list of -- Ralph Hall, you gave us your list of guidances that you think we should focus on for prioritizing. And I just wonder if other stakeholders have a list of a top three to five you'd like to share with us?

And maybe I'll turn to Sharon first because I know you go through this exercise.

MS. SEGAL: Well, in our comments on the last list, we, of course, encouraged finalizing guidances and so on. But the ones that were not included that were important to us included an update on the PMA modifications guidance; manufacturing site changes guidance; the final IDE clinical investigation -- decisions on IDEs; UDI, not the database; and there was some -- quite a few device-specific guidances as well that came from

various, you know, parts of our association, but one of them being the LDTs.

MS. STADE: Heather?

MS. ROSECRANS: I would say off the top of my head I think the antimicrobial guidance and the infusion pump guidance and probably the overall 510(k) program guidance would be the top three that I normally hear about.

MS. STADE: Paul?

MR. BROWN: You know, we haven't actually formally gone through the process to prioritize these. I guess we should obviously. But we're definitely, you know, interested in some of the ones that are on the list here, and I can just tick those off for you: de novo process; the 510(k) program, which Heather just mentioned; and then the benefit to risk in premarket notifications. Those would be the three off the current list that would be top for us.

MS. STADE: Okay. Ralph, you already gave us yours, Ralph Hall. Hans?

MR. BEINKE: Ralph and I talked about his list. I agree with much of his list, except that he left off one of my favorites, which you know is the contrast.

MS. STADE: Not CDRH guidance, but understood.

MR. BEINKE: Okay. I understand.

MS. STADE: Fair enough. Understood. We're one agency.

Ralph Brindis?

DR. BRINDIS: So, I guess my goal is not to reiterate some of the excellent ones that have already been talked about, and particularly on Brother Ralph's list.

I'm going to raise one or two new ones. One is kind of near and dear to me, which is the utilization of registries for postmarket -- for the postmarket approval studies, IDE studies, premarket studies, and developing a good process around those. Another, again, focusing on registries, is the role of registries in these processes in terms of patient consent, and in terms of what type of use of registries require patient consent, retrospectively and prospectively, in the utilization of registries for supporting safety and efficacy in some of our studies.

MS. STADE: And I'll just open it up -- I don't know if folks have any idea -- just more generally what we should consider in prioritization. And I know, Paul, we heard from you that we should really look to the public health need, and I heard also that, you know, there's a patient benefit, although that's not always easy to assess necessarily, but we can take it that's a sort of broad based criteria.

Do folks have any other ideas about just in general how we should -- if we're to develop a list of criteria and this is the list that we're going to use, you could imagine a number of criteria. For example, is it a draft that's more than a year old? What is the public health need?

What are some other criteria what we might consider, if we were to be a little bit more scientific about how we do our prioritization process? And I'll just put on the table now, we have a process. We try to have a rational process. I wouldn't say it' s a scientific process.

Leslie?

MS. KUX: One thing I know some of the other Centers think about is how much response was there to the draft? How many comments did they get on the draft? Are they going to have to make many changes at all? On the thinking that those guidances that go -- you know, that don't need a lot of change between draft and final are much easier to clear through the Agency. So, on the other hand, there may be -- that maybe the fact that they didn't get a lot of comment may be a reason people think it's better to leave them in draft and focus on something else. So, there it's a little bit of the where do you spend your resources?

But I'd be curious to know if people thought it would be valuable just to go ahead and get stuff final, the external stakeholders.

MR. HALL: Well, getting things final is always good. The other thing, which may be implicit, if you listen to the suggestions that came from the various stakeholders, the significant majority were system level types of guidances that have broad impact across individual devices. And so one can extrapolate from that a greater impact from system level guidances. So, a criteria you could consider is the level of impact of the final guidance, what it

would have.

MS. STADE: Right. And that's interesting, of course, if you're looking at on the one hand which are easy to finalize, so, you know, low hanging fruit, versus which have impact probably completely intentioned, but a fair enough point.

So, here's a more specific question and it has to do with the use of the de novo process, which sometimes is accompanied by guidance documents. And, particularly, we see that I think a little bit more in OIR than in ODE, but we do see it in both Offices, where when we do a de novo classification, one of the outputs of that process is a special controls guideline to actually tell us -- tell the world how those devices going forward are going to be reviewed.

And I'm curious from our review offices what the impact is of developing de novo guidelines on the overall guidance program, and also on prioritization. And if you want to speak a little bit to timeline and resources, that'd be, I think, very interesting.

MR. McFARLAND: I guess I'll go first. So, as far as the de novo process, I think my office probably did the vast number, at least historically, of the special controls guidelines for de novo devices. With the changes in FDASIA, there has been, at least in my office, a dramatic spike in the number of de novos that we're reviewing, multitudes. And as a result, whereas it was usually feasible to do a couple of these a year and get out one of these

special controls guidelines, it's not really feasible when you're handling probably almost one every week.

Before we were doing these, it would be a all hands on deck to draft one of these documents because basically you're collapsing an entire guidance review process into 60 days, 90 days, if we have kind of an idea what's coming in. And I would say it's at least as much work as doing a regular guidance document, if not more. So, for us it's become just -- we've gone to usually doing regulations. I'm not going to say we'd never do one again in the future, but just that's in general, I think, our reaction is to go to doing regulations in our de novo orders.

MS. KRUEGER: ODE is doing the same thing. I think we have also seen an uptick in the number of de novos that we are receiving since FDASIA. And we're putting those special controls in the regulation and haven't been prioritizing guidance document or guidelines specific for the de novo classifications at this point.

MS. STADE: And I'll just comment on that a little bit that, you know, when you have the product-specific guidances, that's where you might really have, you know, interference in resources at the Office level because those are driven so much at the Office level. The cross-center guidance documents, the prioritization, you know, obviously it's affecting Center level resources and also external review resources, and to some extent also the Office resources. But it might not be competing for the same -- you might be

competing for two different sets of resources, I guess, is all the point I'm trying to make.

So, on prioritization, I guess before I turn it over -- because I do have a number of questions that have come in that -- and I think I want to start the question and answer process. Maybe I'll just sort of turn it over to the other panelists and see if there are any questions you'd like to ask me or one another about either prioritization or just best practices before we go to the questions and answers.

(No response.)

MS. STADE: All right. So, I said this morning -- there were some questions that came in that we weren't able to get during the first question and answer session, but I do want to get to them now. And they in all cases identify who the questions are directed to.

So, I'm going to turn to these and after I -- after we respond to these, there will be an opportunity for folks both from the webcast and also in the audience to ask questions of anyone on the Panel. Here's your chance.

So, here are a couple questions for me. And the question is: With respect to the analysis of public comments, does FDA review comments as they are received, or does the review process commence only after all comments have been received?

We do sometimes find that we have no comments until day 90, or maybe one or two. If it's one of our more, you know, high priority

guidance documents, you know, there will be some of us who a little bit -- I want to say, you know, a little bit of OCD -- will be checking regulations.gov all the time and seeing what's coming in. But, you know, the process is to look at the docket at the end of the comment period -- that's the standard process -- and look at all comments and start analyzing them then. But there will be, you know, typically at least someone involved in that guidance document who's very interested and will be checking it more frequently and probably will have some idea of how to respond.

So, I would say it's a little bit of both, but probably before we start really responding to the comments document -- to the full, the full number of comments that we've received, there will be someone interested enough in what we're hearing to have reviewed and started thinking about the comments that come in. And I do think if they came in, you know, if they came in over that full comment period, there would be more of a tendency to start the analysis process sooner. But we just find so many of them come in at the end that that's really when we gear up to do the full and out charting analysis and then responding.

I have another question directed to me. And the question is: How does FDA decide when a response is warranted if comments are received on a final guidance? Are multiple comments on the same topic needed, or can one proper relevant comment trigger a re-review of a final guidance?

You know, if a comment comes in after the guidance process -- well, let me start by saying once we have a final guidance, you know, it has gone through the GGP process. So, we've published a draft, we've considered comments. Sometimes there have been some additional processes beyond what's in 10.115 that we've considered. So, we do like to think the final -- at least when it's still current, and the whole question of, you know, obsolescence is another question. But at least when it's still current, it at least has the legitimacy of having gone through the process.

So, when does something come to our attention that could cause us to say, oops, we got it wrong? I think it would have to be pretty significant to reopen the guidance right at the end of the period. That's not to say it couldn't happen. And certainly, in that case, you know, hearing it from more than one source would be, you know, would be more meaningful and more likely to have impact than just hearing it from one source.

But, you know, I am aware of instances where comments on final guidances have caused us to begin the process of reopening the final guidance, even if it didn't result in the final guidance being pulled. It's just initiated a process that is likely ultimately to lead to a new draft being issued.

Here's a question for you, Leslie. So, one suggestion for improving access to guidance documents is to standardize location on FDA Centers' websites and use the same description across all Centers, e.g., newly added and recently added, both used to indicate newly available guidance

documents.

And I wonder, Leslie -- I think you touched on this a little bit -- if you could talk a little bit about, you know, the limitations and also the opportunities in managing our guidance websites.

MS. KUX: You know, I think we're -- as I understand it, and I'm getting a little bit out of depth here, what we're -- what we want to achieve is a single portal that then links to the guidances that are available sort of on the home site, on the home -- on the Internet sites, the home -- the Centers' individual sites. You know, as you might imagine, standardization across the different Centers at FDA is something I don't ask for except with a very good justification because, you know, I value my life.

And so I think that we're trying to at least have a good central portal. The Centers all organize guidances differently. I'm learning a little bit about the way CDER characterizes guidances right now, you know, because of a guidance that I'm working on. And so I think -- I really want to be careful about fixing what's broken but not messing with what people are already used to. One thing we have learned is that the way we name guidances makes them very hard to find.

And so we are going to put in place a different format for naming guidances, so that when you search for them either on Google or on our own website -- I find Google more useful, personally -- you know, they'll come up, they'll come up easier. And other Centers -- some Centers have

numbers, for example, other Centers don't, and, you know, that Center would be very upset if I took numbers out of the guidance title, and their industry would also be very upset because they're used to it.

So, those are some of the considerations I have to deal -- that we have to deal with as we, you know, as we try and make it easier to find the guidances. I'm not sure you can expect standardization, but, hopefully, they'll still be easier to find.

MS. STADE: I don't want to put you on the spot, but I will. Just do you have any comment on the idea of having separate lists of drafts and finals?

MS. KUX: No.

MS. STADE: Okay.

MS. KUX: I mean I'm -- again, I think that would, I think that would be very helpful, but it's, you know -- and it's something we've, you know, we've -- you know, we can certainly consider it. Again, partly it depends on how things are organized across the Agency, but I think it would be very useful.

MS. STADE: And let me -- I put you on the spot. I know even less than you do, but I just -- I do that because I do want folks to understand the website issue. It's not one that we're ignoring. It's one there are technical challenges and sort of organizational challenges to addressing. I do remember the old system we had where there's an index -- for CDRH, at least.

I actually don't know if other Centers did it this way.

There's an index of topics, and it's very nice. You know, if a guidance addressed more than one topic, you could actually find it under both, you know, both places in the index. And I found it very easy to use. I'm told there are -- you know, it's not just folks are saying no you can't do that. There are technical challenges to doing that, but folks are trying to look at what can be done, so that's that.

We have another question about -- this is from over the webcast. Do you have or is it possible to have different processing timelines for high priority guidances versus low priority guidances?

And so we do have that. That's contemplated in our procedures. We have, you know, aspirational time frames for how long a review is going to take. You know, different individuals and organizations have different success in keeping to those timelines, but I would say, you know, people take them seriously. And we have timelines for high priority and for low priority. And I would say, overall high priority are reviewed more quickly, but there is the phenomenon of the high priority document taking much longer just because people are much more interested.

And the other thing folks should just be aware of that sometimes a high priority guidance is a guidance that also has citizen petitions attached to it, or it might have congressional inquiries, or it has other things that also need to be responded to, you know, possibly at the

same time that we respond to the guidance document. And in those cases, we do apply more resources to getting the response out, but it doesn't necessarily mean that the response happens quicker. But we do have different aspirational timelines and slightly different processes.

Okay. So, here's a question related to some of the other recommendations we heard about having, you know, an opportunity for input before we put a draft guidance out. And the specific question is: Is it possible to have a system similar to rulemaking where FDA could do an advance notice of proposed guidance development, like rulemaking has advanced notice of proposed rulemaking? The intention isn't to have guidance equal to regulation, but to give a heads up to stakeholders early in development process for guidances so awareness and transparency for stakeholders is increased and sooner in stages of development.

I think we've commented on that. I think just the nomenclature makes me nervous just because it does become so much more like a rulemaking. At the same time, you know, we're hearing this interest in having a heads up. And, you know, there's a little bit of heads up with our priority list. I'm not going to say that's perfect both because the priority list is incomplete and it doesn't necessarily provide anything like a problem statement for the guidance. It is really nothing more than a heads up.

Could we do something a little more than what we're doing now? I think, you know, the discussion today has been very helpful in teeing

up that issue. And, again, you know, having us consider whether for specific guidance documents we do it, and do it very self-consciously in a way that folks know that this is what we're doing and look at how that works out.

So, that's what I have from the web and also written down on cards. But I'm wondering if we have folks in the audience who would like to ask some additional questions about best practices, about priorities, about other issues that you heard discussed today?

MS. KUX: I have a question, I guess, to follow up on this issue of early thinking. You know, one of the concerns we -- and this reflects another concern that we hear that, you know, what is the status of a draft guidance versus a final guidance? And concern that we're -- you know, that people are being held to policies or standards in draft guidance.

How would we be able to alleviate people's concerns that if we were doing early thinking documents, that we wouldn't get a similar -- you know, even now you have -- now there's another document that they're using to articulate policy that they're going to hold us to, because that, you know, that would be my concern that it would backfire against us possibly in that way.

MS. STADE: Ralph Hall?

MR. HALL: You may want to think about differentiating seeking early input on solutions from early input on the issues or the challenges that you see, and seeking ideas or attributes or pitfalls to avoid.

MS. STADE: Let's just follow up a little bit because I really am interested in hearing folks' thoughts about that. You know, if we were able to issue something more like a document -- because as I said, we do find that the comments on something that's in writing and that's kind of fleshed out tend to be much more robust and actionable than comments, you know, that -- in response to a more open-ended question.

But would there be concern if we moved to that model? And even understanding that, you know, we would have training and we would try to identify the documents is very clearly intended for discussion, not intended -- not even, you know, intended to capture draft current thinking, but really intended to generate conversation, you know, would there be concern with that approach? Or are there certain areas where that could be helpful and other areas where we probably shouldn't go there?

Hans?

MR. BEINKE: Yeah, I mean I think you said it. I mean the key is the orientation that you provide with that. If you make it clear that that's the purpose and a clear statement that this is not establishing policy, I think it's fine. Similar to what we said about documents that are really just -- or guidance documents that are just codifying what's already happening within the Agency. So, I think it can work.

MS. STADE: Ralph Brindis?

DR. BRINDIS: So, I'm at a disadvantage, Leslie, because I have

never had to sit in your seat or wear Kevlar and get those calls, so I -- so tempering that comment, I actually just view that I would -- most external stakeholders would view this as a positive, proactive reach out from the Agency, in terms of trying to figure out with you the scope and the breadth of what the document is. Again, you're not saying this is what the solution is. It's helping craft with you, or advise you, as to scope and breadth, I would view as being viewed very positively as opposed to putting in a dictum early on of a policy.

MS. STADE: Sharon, and then Ruth.

MS. SEGAL: I think it would be helpful if for only it sets forth some sort of consistent approach, as opposed to come see us on a one-on-one basis and getting different advice from different reviewers. It would help for a level playing field, is what I'm trying to say, and there would be more consistency. And in that regard, I think it would be helpful.

MS. KUX: Of course, that sort of cuts the other way, but I take your point. To the extent we have experience, we can reflect our experience in an early thinking document, I guess, whatever you want to call it.

MS. STADE: Ruth.

MS. FISCHER: Since I've been in the trenches for many years, I have a slightly different take. And here are a couple of things that I've heard. First of all, in our guidance documents, when we refer to other documents, and they're final, but we also have a draft that's out for comment, we list

both. And with the draft, we also say this represents FDA's current thinking.

So, I have heard that the manufacturer doesn't know if they're supposed to be going with the old guidance document or if they're supposed to be gearing up with FDA's current thinking, and that it takes time for them to make the conversion, so the conversion is going on during the draft period. So, that's a point of just language confusion, I think.

MS. STADE: Any additional comments or questions?

I'll follow up a little bit on the idea that, you know, we could do something even pre-draft and have that, you know, provide additional consistency. And I think that's exactly -- you know, that's the real challenge is where, you know -- can we -- and I'm not sure that we can -- can we provide additional clarity without going through the complete guidance process versus, you know, can we just produce documents that are really intended to generate the best discussion from when we actually produce a final and have it marked and clearly, very clearly represented as not current thinking, not draft current thinking, but just as something maybe FDA would do, what do you think?

Hans?

MR. BEINKE: I mean I think part of the problem that we have had is when you do go -- I mean to me it just seems like a lot of effort to have a draft document and to then get comments. And to get some sort of scope, objective, to get that kind of upfront input would seem to avoid a lot of pain

later on and wasted time to put something together where there's a big disconnect.

MS. STADE: And so, let me ask you, where do you think stakeholders -- and I'll direct this to industry, but folks, other stakeholders can comment also. What types of information do you think is the most useful? Is it on a device-specific guidance where, you know, you have an expert on this technology who can provide information? Or is it policy, legal? Where else can we most benefit from input?

MR. BEINKE: To me it's more the cross-cutting policy -- I mean those are the tough ones. I'm assuming that on a product level, you've got people that are in the trenches, both FDA and industry, that can work on that. There are probably already some existing understandings. I see that as something that should be relatively straightforward. It's the other that gets very complex.

MR. HALL: I agree with that because of the broader impact of those types of guidances and the extensive cross-linkages with other programmatic documents, and the whole challenge of unintended consequences. You don't commonly get unintended consequences with a device specific. It's much more probable to get unintended consequences with a programmatic. And that's where having lots of minds looking at it, you know, you get that, oh, wait, see what it would do over here.

MS. STADE: Ruth and -- it's okay.

AUDIENCE: I was just going to add to a different perspective with the draft and where the concept, paper concept may be more useful is. It's really when there's like a significant change in Agency policy and Agency thinking from the current way that, you know, that's where there's the most angst. You know, I think of the 510(k) modifications guidance as an example where there was concern that it was such a significant change and having some advance discussion would be beneficial. That also applies in some cases to some device-specific guidance as well.

There have been some where the draft guidance is drastically different than current practice. You know, in the 510(k) arena where a manufacturer may have extensive experience with multiple 510(k)s, and then the draft comes out and has a different set of criteria. And just that uncertainty in that period between the issuance of the draft to eventually getting to something final when there's knowledge that there are a lot of comments going in proposing alternatives, that that uncertainty really is difficult to deal with from a business perspective.

MS. STADE: Ruth?

MS. FISCHER: I'm just wondering are you suggesting, if we have -- let's just call it a discussion paper -- that this paper is -- that the notice of this paper goes in the *Federal Register* or is just distributed, as we get more and more documents, guidance documents that are combinations from the industry perspective, the consumer perspective, and the patient perspective,

all at once, we have to notify everyone that it's available. So, what's the way to do that legally?

MS. STADE: And so, let me just address that a little bit, Ruth, because I think there have been a few cases where we've tried to do something like that. And what we've tried to do to avoid having it seem like, you know, a process, an impermissible process outside GGPs is we've tried to do it as part of a public forum. And so, the discussion can be public. The document can be made publicly available, and, you know, we can make sure because it's being -- the discussion is public that it's not represented as our current thinking. It's represented as something that we just want -- we want folks to react to.

MS. FISCHER: So, then just target the high priority topics for that because it takes a lot of work to put on a public workshop.

MS. STADE: It does. And I think that's an underlying theme to a lot of what we're talking about was, you know, additional processes are great. There can be costs to additional processes, but they may well be worth it.

Any more questions?

(No responses.)

MS. STADE: Are you sure?

Okay. Well, I'm just going to take a very short amount of time to wrap up. First of all, I really want to thank our panelists from FDA and also

outside FDA for participating in what I think was an extraordinarily constructive conversation. And a lot of the ideas we're hearing today, I think for the most part there's a little bit more specificity around some of the ideas, but most of them aren't new. And so why haven't we been implementing these ideas?

It's a little bit like the guidance program. We have to prioritize and sift through the ideas and decide how much -- how they can be integrated into our current processes. But I do think this was intended as a trial balloon. Is this something that can be useful on a more regular basis? I think we're going to be looking at that closely and looking at the suggestions and thinking harder about, you know, the consequences of the suggestions for how our program is currently operating.

And I'm speaking about the CDRH program, but I know Leslie is also very forward looking in the Agency program, and I'm sure we'll be having additional conversations as well about how and whether these can be implemented and, you know, again, just the consequences to how things are running.

But with that, I think I'm going to close out today's session. Again, I think the recommendations were very, very useful and very, very helpful, and I really look forward to circling back with Jeff, with Leslie, with my team, and talking about both -- you know, how some of these can be implemented, whether they can be implemented, and also, you know, how

we close the loop with our stakeholders because I know you're going to be interested, now that we've heard from you, what we're going to do about it.

Thanks very much, everyone.

(Whereupon, at 3:16 p.m., the meeting was adjourned.)

C E R T I F I C A T E

This is to certify that the attached proceedings in the matter of:

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PRIORITIZATION WORKSHOP

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Silver Spring, Maryland

were held as herein appears, and that this is the original transcription thereof for the files of the Food and Drug Administration, Center for Devices and Radiological Health.

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Cathy Belka

Official Reporter